PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Docket No. BESSON ET AL (CON-2)
Anticipated Classification of this application:
Class ___ Subclass ___
Prior application: 08/985,673
Examiner: S. GETZOW
Art Unit: 3305

Commissioner of Patents and Trademarks
Washington, D.C. 20231

FILING UNDER 37 CFR 1.53

This is a request for filing a

X Continuation
__ Divisional

application under 37 CFR 1.53, of pending prior application

serial no. 08/985,673 filed on 12/5/97
(date)

of MARCUS BESSON ET AL
(inventor(s))

for WIRELESS MEDICAL DIAGNOSIS AND MONITORING EQUIPMENT
(title of invention)

CERTIFICATION UNDER 37 CFR 1.10

I hereby certify that this 37 CFR 1.60 request and the documents referred to as attached therein are being deposited with the United States Postal Service on this date August 24, 1999 in an envelope as "Express Mail Post Office to Addressee" service under 37 CFR 1.10, Mailing Label No. EL 414622482US addressed to the: Commissioner of Patents and Trademarks, Washington, D.C. 20231.

Ingrid Mittendorf
(Type or print name of person mailing paper)

(Signature of person mailing paper)

NOTE: Each paper or fee filed by "Express Mail" must have the number of the "Express Mail" mailing label placed thereon prior to mailing (37 CFR 1.10(b)).

R \LIZ\899 docs\BESSON-CIP transmittal wpd wpd

1. Copy of Prior Application as Filed Which is Attached

The copy of the papers of prior application as filed which are attached are as follows:

X 71 page(s) of specification

X 11 page(s) of claims

X 1 page(s) of abstract

X 6 sheets(s) of drawings

(Also complete part 6 below if drawings are to be transferred)

X 2 pages of declaration and power of attorney

If the copy of the declaration being filed does not show applicant's signature in indicate thereon that it was signed and complete the following:

— in accordance with the indication required by 37 CFR 60(b) my records reflect that the original signed declaration showing applicant's signature was filed on _____

— the amendment referred to in the declaration filed to complete the prior application and I hereby state, in accordance with the requirements of 37 CFR 1.60(b), that this amendment did not introduce new matter therein.

2. Amendments

X Cancel in this application original claims 1 - 45 of the prior application before calculating the filing fee. (At least one original independent claim must be retained for filing purposes.)

X A preliminary amendment is enclosed. (Claims added by this amendment have been properly numbered consecutively beginning with the number next following the highest numbered **original** claim in the prior application.)

3. Petition for Suspension of Prosecution for the Time Necessary to File an Amendment

Note: Where it is possible that the claims on file will give rise to a first action final for this continuation application and for some reason an amendment cannot be filed promptly (e.g., experimental data is being gathered), it may be desirable to file a petition for suspension of prosecution for the time necessary.

(check the next item, if applicable)

___ There is provided herewith a Petition to Suspend Prosecution For The Time Necessary to File an Amendment (New Application Filed Concurrently).

4. Fee Calculation

CLAIMS AS FILED

Number filed	Number Extra		Rate	Basic Fee	$ 760.00
Total claims 66-20=	46	x	$ 22.00		$ 1012.00
Independent Claims (37 CFR 1.16(b)) 4-3=	1	x	$ 78.00		$78.00
Multiple dependent claim(s), if any (37 CFR 1.16(d))	0	0 x	$220.00		0

___ Fee for extra claims is not being paid at this time (37 CFR 1.16(d))

NOTE: If the fees for extra claims are not paid on filing they must be paid or the claims canceled by amendment, prior to the expiration of the time period set for response by the PTO in any notice of fee deficiency. 37 CFR 1.16(d)).

Filing Fee Calculation $ 1850.00

5. Small Entity Status

_X_ A verified statement that this filing is by a small entity:

___ is attached

_X_ has been filed in the parent application and such status is still proper and desired (37 CFR 1.28(a)).

Filing Fee Calculation (50% of above) $ 925.00

NOTE: Any excess of the full fee paid will be refunded if a verified statement is filed within 2 months of the date of timely payment of a full fee; then the excess fee paid will be refunded upon request. 37 CFR 1.28(a).

NOTE: 37 CFR 1.28(a), last sentence, states: "Applications filed under § 1.60 or § 1.62 of this part must include a reference to a verified statement in a parent application if status as a small entity is still proper and desired."

6. Drawings

*WARNING: Do **not** check the following box if prior case is not to be abandoned.*

___ Transfer the drawings from the prior application to this application and, subject to item 17 below, abandon said prior application as of the filing date accorded this application. A duplicate copy of this request is enclosed for filing in the prior application file. *(May only be used if signed by (1) applicant, (2) assignee of record or (3) attorney or agent of record authorized by 37 CFR 1.138 and before payment of issue fee.)*

NOTE: *"A registered attorney or agent acting under the provisions of § 1.34(a), or of record, may also expressly abandon a prior application as of the filing date granted to a continuing application when filing such a continuing application." 37 CFR 1.138.*

___ Transfer the following sheet(s) of drawings from the prior application to this application

_____

NOTE: *Transferred sheets must be canceled in the prior application. 37 CFR 1.88.*

___ A copy of the amendment canceling these sheets of drawings in the prior application is attached.

_X_ New drawings are enclosed

_X_ formal

___ informal

WARNING: *DO NOT submit original drawings. A high quality copy of drawings should be supplied when filing a patent application. The drawings that are submitted to the Office must be on strong, white, smooth, and non-shiny paper and meet the standards of § 1.84. If corrections to the drawings are necessary, they should be made to the original drawings and a high-quality copy of the corrected original drawing then submitted to the Office. Only one copy is required or desired. Comments on proposed new 37 CFR 1.84. Notice of March 9, 1988 (1090 O.G. 57-62).*

NOTE: *"Identifying indicia such as the serial number, group art unit, title of the inventor, attorney's docket number, inventor's name, number of sheets, etc. not to exceed 2¾ inches (7.0 cm) in width may be placed in a centered location between the side edges within three-fourths inch (19.1 mm) of the top edge. Either this marking technique on the front of the drawing or the placement, although not preferred, of this information and the title of the invention on the back of the drawings is acceptable." Proposed 37 CFR 1.84(1). Notice of March 9, 1988 (1090 O.G. 57-62).*

7. Priority - 35 U.S.C. 119

_X_ Priority of application serial no. 0 / P4329828.2 filed on ___ September 4, 1993 in Germany is claimed under 35 U.S.C. 119. *(country)*

This application was filed as a PCT application on September 2, 1994 having application number PCT/EP94/02926. A certified copy of the priority application was filed with the international bureau.

___ The certified copy has been filed in prior U.S. application serial no. 0 / _____ on _____

___ The certified copy will follow.

8. Relate Back - 35 U.S.C. 120

_X_ Amend the specification by inserting before the first line in the sentence:

"This is a

_X_ continuation

___ divisional

of copending application(s)

_X_ Serial number 08/985,673 filed on 12/5/97, which is a continuation of Serial No. 08/605,197 filed on March 1, 1996

and

_X_ International Application PCT/EP94/02926 filed on 9/2/94 and which designated the U.S."

NOTE: The proper reference to a prior filed PCT application which entered the U.S. national phase is the U.S. serial number and the filing date of the PCT application which designated the U.S.

9. Inventorship Statement

NOTE: If the continuation or divisional application is filed by less than all the inventors named in the prior application a statement must accompany the application when filed requesting deletion of the names of the person or persons who are not inventors of the invention being claimed in the continuation or divisional application. 37 CFR 1.60(b) [emphasis added].

(complete appropriate items (a) and (b))

(a) With respect to the prior copending U.S. application from which this application claims benefit under 35 U.S.C. 120, the inventor(s) in this application is (are):

(complete applicable item below)

_X_ the same

___ less than those named in the prior application and it is requested that the following inventor(s) identified above for the prior application be deleted:

_____

(Type name(s) of inventor(s) to be deleted)

(b) The inventorship for all the claims in this application are

_X_ the same

___ not the same, and an explanation, including the ownership of the various claims at the time the last claimed invention was made, is submitted.

10. Assignment

___ The prior application is assigned of record to

_____

___ an assignment of the invention to _____

_____

is attached

11. Fee Payment Being Made At This Time

___ Not Enclosed

___ No filing fee is submitted. *(This and the surcharge required by 37 CFR 1.16(e) can be paid subsequently).*

_X_ Enclosed

_X_ basic filing fee $ 925.00

___ recording assignment ($40.00; 37 CFR 1.21(h)) $ _____

___ processing and retention fee ($120.00; 37 CFR 1.53(d) and 121(l)) $ _____

NOTE: 37 CFR 1.21(l) establishes a fee for processing and retaining any application which is abandoned for failing to complete the application pursuant to 37 CFR 1.53(d) and this, as well as the changes to 37 CFR 1.53 and 1.78, indicate that in order to obtain the benefit of a prior U.S. application, either the basic filing fee must be paid or else the processing and retention fee of § 1.21(l) must be paid within 1 year from notification under § 53(d).

Total fees enclosed $ 925.00

12. Method of Payment of Fees

X enclosed is a check in the amount of $ 925.00

___ charge Account No. _____ in the amount of $ _____.
A duplicate of this request is attached.

NOTE: Fees should be itemized in such a manner that is clear for which purpose the fees are paid. 37 CFR 1.22(b).

13. Authorization to Charge Additional Fees

WARNING: If no fees are being paid on filing do not complete this item.

WARNING: Accurately count claims, especially multiple dependent claims, to avoid unexpected high charges if extra claim charges are authorized.

X The Commissioner is hereby authorized to charge the following additional fees which may be required by this paper and during the entire pendency of the application to Account No. 03-2468 .

X 37 CFR 1.16(a), (f) or (g) (filing fees)

X 37 CFR 1.16(b), (c) and (d) (presentation of extra claims)

NOTE: Because additional fees for excess or multiple dependent claims not paid on filing or on later presentation must only be paid or these claims canceled by amendment prior to the expiration of the time period set for response by the PTO in any notice of fee deficiency (37 CFR 1.16(d), it might be best not to authorize the PTO to charge additional claim fees, except possibly when dealing with amendments after final action.

X 37 CFR 1.17 (application processing fees)

WARNING: While 37 CFR 1.17(a), (b), (c) and (d) deal with extensions of time under § 1.136(a), this authorization should be made only with the knowledge that: "Submission of the appropriate extension fee under 37 CFR 1.136(a) is to no avail unless a request or petition for extension is filed." [emphasis added]. notice of November 5, 1985 (1060 O.G. 27).

___ 37 CFR 1.18 (issue fee at or before mailing Notice of Allowance, pursuant to 37 CFR 1.311(b)).

NOTE: Where an authorization to charge the issue fee to a deposit account has been filed before the mailing of a Notice of Allowance, the issue fee will be automatically charged to the deposit account at the time of mailing the Notice of Allowance. 37 CFR 1.1311(b).

NOTE: 37 CFR 1.28(b) requires "Notification of any change in status resulting in loss of entitlement to small entity status must be filed in the application ... prior to paying or at the time of paying ... issue fee." Form the wording of 37 CFR 1.28(b): (a) notification of change of status must be made even if the fee is paid as "other than a small entity" and (b) no notification is required if the change is to another small entity.

14. Power of Attorney

X The power of attorney in the prior application is to

Allison C. Collard	22,532
Attorney	*Reg. No.*
Edward R. Freedman	26,048
Attorney	*Reg. No.*
Edwin H. Keusey	34,361
Attorney	*Reg. No.*

a. X The power appears in the original papers in the prior application.

b. ___ Since the power does not appear in the original papers, a copy of the power in the prior application is enclosed.

c. ___ A new power has been executed and is attached.

d. _X_ Address all future communications to:

Edward R. Freedman
1077 Northern Boulevard
Roslyn, New York 11576

(item d may only be completed by applicant, or attorney or agent of record)

15. Maintenance of Copendency of Prior Application

*(This item must be completed and the papers filed in the **prior** application if the period set in the prior application has run.)*

___ A petition, fee and response has been filed to extend the term in the pending prior application until _____.

NOTE: The PTO finds it useful if a copy of the petition filed in the prior application extending the term for response is filed with the papers constituting the filing of the Continuation Application. Notice of November 5, 1985 (1060 O.G. 27).

___ A copy of the petition for extension of time in the prior application is attached.

16. Conditional Petition for Extension of Time in Prior Application

(complete this item and file conditional petition in the prior application if previous item not applicable)

___ a conditional petition for extension of time is being filed in the pending parent application.

NOTE: The PTO finds it useful if a copy of the petition filed in the prior application extending the term for response is filed with the papers constituting the filing of the Continuation Application. Notice of November 5, 1985 (1060 O.G. 27).

___ A copy of the conditional petition for extension of time in the prior application is attached.

17. Abandonment of Prior Application (if applicable)

WARNING: (Do not complete this item if the application being filed is a divisional of the prior application which is not being abandoned)

NOTE: "A registered attorney or agent acting under the provisions of § 1.34(a), or of record, may also expressly abandon a prior application as of the filing date granted to a continuing application when filing such a continuing application." 37 CFR 1.138.

___ Please abandon the prior application at a time while the prior application is pending or when the petition for extension of time or to revive in that application is granted and when this application is granted a filing date so as to make this application copending with said prior application.

Edward R. Freedman
Type or print name of person signing

August 24, 1999
Date

Signature

1077 Northern Boulevard
P.O. Address of Signatory

Roslyn, New York

Tel. No.: (516) 365 9802

Reg. No. 26,048
(if applicable)

___ Inventor

___ Assignee of complete interest

___ Person authorized to sign on behalf of assignee

_X_ Attorney or agent of record

___ Filed under Rule 34(a)

(Complete the following if applicable)

Type name of assignee

Address of assignee

Title of person authorized to sign on behalf of assignee

Assignment recorded in PTO on _____

Reel _____ Frame _____

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

APPLICANT: MARCUS BESSON ET AL.

FOR: WIRELESS MEDICAL DIAGNOSIS AND MONITORING EQUIPMENT

PRELIMINARY AMENDMENT

Hon. Assistant Commissioner for Patents
Washington, D.C. 20231
Attn: BOX PATENT APPLICATION

Dear Sir:

Preliminary to examination, please amend the above-identified patent application as follows:

IN THE SPECIFICATION:

Page 7, after line 2, please insert:

--A device for acquiring the measured data of body functions is known from WO 87/06113. This device has a covering, within which provision is made for sensors for detecting the temperature, pressure, as well as bioelectric and optic signals. These signals are converted by means of an analog-to digital converter into digital values processed by a microprocessor. The microprocessor is connected to a transmitting and receiving unit for wireless data transmission via a serial interface. These data are transmitted from or to an evaluator station, which evaluates the quantities determined by the sensors. The data transmitted from the evaluator station to the electrode are used, for example, for administering a

current pulse to the monitored animal. However, this device has the drawback that, especially with great transmission distances, the signals received become so weak that safe transmission of the data is no longer assured. This can be compensated only by selecting the transmitting power of the evaluator station and of the electrode sufficiently high, so that the safe data transmission is assured even over the greatest possible distance of transmission. This, however, leads to very high current consumption and thus to a very short useful life of the electrode.--.

Page 13, line 4, please delete "relativelt" and insert --relatively--.

Page 18, line 4, please delete "arrang3ed" and insert --arranged--.

Page 18, line 5, please delete "coees" and insert --codes--.

Page 33, line 7, please delete "is" and insert --in--.

Page 45, line 4, after "the" (last occurrence), insert --electrodes--.

Page 43, line 13, please delete "plan view and"; line 15, please delete "plan view and"; line 17, please delete "plan view and".

Page 43, line 19, please insert:

--Fig. 2d shows a plan view of the electrode shown in Fig. 2a;

Fig. 2e shows a plan view of the electrode shown in Fig. Fig. 2b; and

Fig. 2f shows a plan view of the electrode shown in Fig. 2c; --.

Page 44, line 1, please delete "4" and substitute therefor --4a--; line 2, please delete ", with a measured curve"; line 3, please insert, --Fig. 4b shows a measured curve for the electron shown in Fig. 4a.--.

Page 55, line 16, after "2a", please insert --, Fig. 2d--; after "2b", please insert --, Fig. 2f--.

Page 57, line 1, please delete "Fig. 2a shows" and substitute therefor --Figs. 2a and 2d show--; line 8, please delete "Fig. 2b shows" and substitute therefor --Figs. 2b and 2e show--.

Page 58, line 4, please delete "Fig. 2c shows" and substitute --Figs. 2c and 2f show--.

Page 61, line 21, please delete "4" and insert --4a--.

Page 62, line 22, please delete "4" and insert --4b--.

IN THE CLAIMS:

Please cancel claims 1-45.

Please add new claims 46-111 as follows:

46. A medical system for acquiring measured data, in particular for monitoring body functions, comprising:

at least one evaluation station having at least one receiver and at least one transmitter for wireless digital data transmission and receiving;

one electrode allocated to each evaluation station and capable of being attached to a patient, said electrode comprising:

at least one sensor for detecting an electric, physical, chemical or biological quantity, and converting the detected quantity into an electric signal;

a covering comprising:

at least one converter for converting the electric signal generated by said sensor into a digital value;

at least one transmitter coupled to said at least one converter for transmitting the digital data to the receiver in said evaluation station; and

at least one receiver for receiving data transmitted by the evaluation station transmitter; and

at least one error diagnosis and correction unit coupled to at least one of said electrode and evaluation station for detecting errors in the received data;

whereby the data transmitted by said evaluation station to said electrode can manipulate the data transmitted by said electrode to the evaluation station.

47. A medical system for acquiring measured data, in particular for monitoring body functions, comprising:

at least one evaluation station having at least one receiver and at least one transmitter for wireless digital data transmission and receiving;

at least two electrodes capable of being attached to a patient, each of said electrodes comprising:

at least one sensor for detecting an electric, physical, chemical or biological quantity, and converting the detected quantity into an electric signal;

a covering comprising:

at least one converter for converting the electric signal generated by said sensor into a digital value;

at least one transmitter coupled to said at least one converter for transmitting the digital data to the receiver in said evaluation station; and

at least one receiver for receiving data transmitted by the evaluation station transmitter,

wherein data transmitted by said evaluation station to said electrode can manipulate the data transmitted by said electrode to the evaluation station.

48. The system according to claim 46, wherein the evaluation station comprises at least one decoding unit and wherein said electrode is equipped with an encoding unit.

49. The system according to claim 46, wherein the evaluation station contains at least one encoding unit and wherein said electrode is equipped with a decoding unit.

50. The system according to claim 46, wherein the evaluation station comprises at least one demultiplexer unit and wherein said electrode is equipped with at least one multiplexer unit.

51. The system according to claim 46, wherein the evaluation station contains at least one multiplexer unit and wherein said electrode contains at least one demultiplexer unit.

52. The system according to claim 46, wherein the evaluation station has at least one of a storage unit, display unit and alarm unit.

53. The system according to claim 46, wherein the evaluation station and electrode have at least one of an electromagnetic detector and emitter, said emitter being designed as a semiconductor diode.

54. The system according to claim 46, wherein said evaluation station further comprises a transmission control unit, said transmission control unit having a synchronization unit that synchronizes the reference frequencies, oscillator frequencies, carrier frequencies, the cycle, the phase and the time frame of the electrode.

55. The system according to claim 46, wherein said electrode further comprises a transmission control unit.

56. The system according to claim 46, wherein the evaluation station further comprises a status unit, said status unit permitting the selection of the electrode to be addressed and automatically recognizing which electrode is connected and correctly connected to the body at the start of the diagnosis or monitoring.

57. The system according to claim 46, further comprising a control unit always adjusting the transmitting power of the signals of the electrode and the evaluation station to the minimum value required for still operating the circuit and transmitter of the electrode, and if the transmitting power required by the electrode is too high, the respective electrode no longer transmits signals to the evaluation station and receives signals transmitted by the evaluation station.

58. The system according to claim 46, further comprising a calibration unit connected to at least one of the evaluation station and electrode.

59. The system according to claim 46, wherein the evaluation station further comprises at least one of an interleaving unit and a deleaving unit and wherein the electrode has at least one of an interleaving unit and deleaving unit.

60. The system according to claim 46, wherein said electrode is attached to the skin surface.

61. The system according to claim 46, wherein said electrode has at least one electrode pin penetrating the body of a patient.

62. The system according to claim 46, wherein said electrode has at least one of an evaluation unit and a storage unit.

63. The system according to claim 47, wherein the evaluation station comprises at least one decoding unit and wherein each electrode is equipped with an encoding unit.

64. The system according to claim 47, wherein the evaluation station contains at least one encoding unit and wherein each electrode is equipped with a decoding unit.

65. The system according to claim 47, wherein the evaluation station comprises at least one demultiplexer unit and wherein said electrodes are equipped with at least one multiplexer unit.

66. The system according to claim 47, wherein the evaluation station contains at least one multiplexer unit and wherein said electrodes contains at least one demultiplexer unit.

67. The system according to claim 47, wherein the evaluation station has at least one of a storage unit, display unit and alarm unit.

68. The system according to claim 47, wherein the evaluation station and electrodes have at least one of an electromagnetic detector and emitter, said emitter being designed as a semiconductor diode.

69. The system according to claim 47, wherein said evaluation station further comprises a transmission control unit, said transmission control unit having a synchronization unit that synchronizes the reference frequencies, oscillator frequencies, carrier frequencies, the cycle, the phase and the time frame of the electrodes.

70. The system according to claim 47, wherein said electrodes further comprise a transmission control unit.

71. The system according to claim 47, wherein the evaluation station further comprises a status unit, said status unit permitting the selection of the electrode to be addressed and automatically recognizing which electrodes are connected and correctly connected to the body at the start of the diagnosis or monitoring.

72. The system according to claim 47, further comprising a control unit always adjusting the transmitting power of the signals of the electrodes and the evaluation station to the minimum value required for still operating the circuit and transmitter of the electrodes, and if the transmitting power required by the electrodes is too high the respective electrode no longer transmits signals to the evaluation station and receives signals transmitted by the evaluation station.

73. The system according to claim 47, further comprising a calibration unit connected to at least one of the evaluation station and electrodes.

74. The system according to claim 47, wherein the evaluation station further comprises at least one of an interleaving unit and a deleaving unit and wherein the electrodes have at least one of an interleaving unit and deleaving unit.

75. The system according to claim 47, wherein said electrodes are attached to the skin surface.

76. The system according to claim 47, wherein each electrode has an electrode pin penetrating the body of a patient.

77. The system according to claim 47, wherein each electrode has an evaluation unit and a storage unit.

78. A medical system according to claim 46, wherein the data transmitted by the evaluation station to said electrode can control the data transmitted by said electrode to the evaluation station.

79. A medical system according to claim 47, wherein the data transmitted by the evaluation station to said electrode can control the data transmitted by said electrode to the evaluation station.

80. A medical system for acquiring measured data, in particular for monitoring body functions, comprising:

at least one evaluation station having at least one receiver and at least one transmitter for wireless digital data transmission and receiving;

one electrode allocated to each evaluation station and capable of being attached to a patient, said electrode comprising:

at least one sensor for detecting an electric, physical, chemical or biological quantity, and converting the detected quantity into an electric signal;

a covering comprising:

at least one converter for converting the electric signal generated by said sensor into a digital value;

at least one transmitter coupled to said at least one converter for transmitting the digital data to the receiver in said evaluation station; and

at least one receiver for receiving data transmitted by the evaluation station transmitter; and

at least one error diagnosis and correction unit coupled to at least one of said electrode and evaluation station for detecting errors in the received data;

whereby the data transmitted by said evaluation station to said electrode can control the data transmitted by said electrode to the evaluation station.

81. A medical system for acquiring measured data, in particular for monitoring body functions, comprising:

at least one evaluation station having at least one receiver and at least one transmitter for wireless digital data transmission and receiving;

at least two electrodes capable of being attached to a patient, each of said electrodes comprising:

at least one sensor for detecting an electric, physical, chemical or biological quantity, and converting the detected quantity into an electric signal;

a covering comprising:

at least one converter for converting the electric signal generated by said sensor into a digital value;

at least one transmitter coupled to said at least one converter for transmitting the digital data to the receiver in said evaluation station; and

at least one receiver for receiving data transmitted by the evaluation station transmitter,

whereby the data transmitted by said evaluation station to said electrode can control the data transmitted by said electrode to the evaluation station.

82. The system according to claim 80, wherein the evaluation station comprises at least one decoding unit and wherein said electrode is equipped with an encoding unit.

83. The system according to claim 46, wherein the evaluation station contains at least one encoding unit and wherein said electrode is equipped with a decoding unit.

84. The system according to claim 80, wherein the evaluation station comprises at least one demultiplexer unit and wherein said electrode is equipped with at least one multiplexer unit.

85. The system according to claim 80, wherein the evaluation station contains at least one multiplexer unit and wherein said electrode contains at least one demultiplexer unit.

86. The system according to claim 80, wherein the evaluation station has at least one of a storage unit, display unit and alarm unit.

87. The system according to claim 80, wherein the evaluation station and electrode have at least one of an electromagnetic detector and emitter, said emitter being designed as a semiconductor diode.

88. The system according to claim 80, wherein said evaluation station further comprises a transmission control unit, said transmission control unit having a synchronization unit that synchronizes the reference frequencies, oscillator frequencies, carrier frequencies, the cycle, the phase and the time frame of the electrode.

89. The system according to claim 80, wherein said electrode further comprises a transmission control unit.

90. The system according to claim 80, wherein the evaluation station further comprises a status unit, said status unit permitting the selection of the electrode to be addressed and automatically recognizing which electrode is connected and correctly connected to the body at the start of the diagnosis or monitoring.

91. The system according to claim 80, further comprising a control unit always adjusting the transmitting power of the signals of the electrode and the evaluation station to the minimum value required for still operating the circuit and transmitter of the electrode, and if the transmitting power required by the electrode is too high, the respective electrode no longer transmits signals to the evaluation station and receives signals transmitted by the evaluation station.

92. The system according to claim 80, further comprising a calibration unit connected to at least one of the evaluation station and electrode.

93. The system according to claim 80, wherein the evaluation station further comprises at least one of an interleaving unit and a deleaving unit and wherein the electrode has at least one of an interleaving unit and deleaving unit.

94. The system according to claim 80, wherein said electrode is attached to the skin surface.

95. The system according to claim 80, wherein said electrode has at least one electrode pin penetrating the body of a patient.

96. The system according to claim 80, wherein said electrode has at least one of an evaluation unit and a storage unit.

97. The system according to claim 81, wherein the evaluation station comprises at least one decoding unit and wherein each electrode is equipped with an encoding unit.

98. The system according to claim 81, wherein the evaluation station contains at least one encoding unit and wherein each electrode is equipped with a decoding unit.

99. The system according to claim 81, wherein the evaluation station comprises at least one demultiplexer unit and wherein said electrodes are equipped with at least one multiplexer unit.

100. The system according to claim 81, wherein the evaluation station contains at least one multiplexer unit and wherein said electrodes contains at least one demultiplexer unit.

101. The system according to claim 81, wherein the evaluation station has at least one of a storage unit, display unit and alarm unit.

102. The system according to claim 81, wherein the evaluation station and electrodes have at least one of an electromagnetic detector and emitter, said emitter being designed as a semiconductor diode.

103. The system according to claim 81, wherein said evaluation station further comprises a transmission control unit, said

transmission control unit having a synchronization unit that synchronizes the reference frequencies, oscillator frequencies, carrier frequencies, the cycle, the phase and the time frame of the electrodes.

104. The system according to claim 81, wherein said electrodes further comprise a transmission control unit.

105. The system according to claim 81, wherein the evaluation station further comprises a status unit, said status unit permitting the selection of the electrode to be addressed and automatically recognizing which electrodes are connected and correctly connected to the body at the start of the diagnosis or monitoring.

106. The system according to claim 81, further comprising a control unit always adjusting the transmitting power of the signals of the electrodes and the evaluation station to the minimum value required for still operating the circuit and transmitter of the electrodes, and if the transmitting power required by the electrodes is too high the respective electrode no longer transmits signals to the evaluation station and receives signals transmitted by the evaluation station.

107. The system according to claim 81, further comprising a calibration unit connected to at least one of the evaluation station and electrodes.

108. The system according to claim 81, wherein the evaluation station further comprises at least one of an interleaving unit and

a deleaving unit and wherein the electrodes have at least one of an interleaving unit and deleaving unit.

109. The system according to claim 81, wherein said electrodes are attached to the skin surface.

110. The system according to claim 81, wherein each electrode has an electrode pin penetrating the body of a patient.

111. The system according to claim 81, wherein each electrode has an evaluation unit and a storage unit.--

REMARKS

By this amendment, Applicants have amended the specification as required during the prosecution of the parent application and have added new claims 46-111, which correspond to original claims 1-45. Independent claims 80 and 81 are similar to claims 46 and except that the word "control" replaces the word "manipulate" in the last paragraph of claims 80 and 81. Claims 82-111 have been added to depend from new claims 80 and 81. These new dependent claims are identical in substance to claims 48-77.

Early allowance of the amended and new claims is respectfully requested.

Respectfully submitted,

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WIRELESS MEDICAL DIAGNOSIS AND MONITORING EQUIPMENT

The invention relates to a medical measured-data acquisition equipment for monitoring and diagnosis, in particular to EEG and EKG equipment, as well as to facilities for controlling the breathing, the O_2 saturation content in the blood, the body temperature, and for recording electric potentials or electrodermal activities such as the SSR (sympathetic skin response). Such monitoring and diagnostic equipment is used mainly in intensive-care stations in hospitals, or in the examination of patients.

Monitoring equipment is used also for monitoring infants at home, among other things. In the Federal Republic of Germany about 2000 infants die annually from the sudden infant death syndrome, a phenomenon, the causes of which have not yet been elucidated in spite of intensive research. owever, everything speaks for the fact that the sudden infant death is to be attributed to a failure of the respiratory function (apnea), and possibly of the cardiac function. It exclusively occurs during sleeping. The only preventive measure for preventing

the sudden infant death currently consists in the monitoring of the respiratory or cardiac function. Said procedure is useful in that by stimulating the infant immediately following failure of the respiratory function, the the respiratory activity automatically starts again, with a few exceptions.

EKG and EEG facilities assume a special position among monitoring and diagnostic devices because their high medical conclusiveness. An electrocardiogram (EKG) is the recording of the time curve of heart action potentials; an electro-encephalogram (EEG) is the graphic record of the brain action potentials. The analysis of the EKG's and EEG's supplies important information about the heart or brain function of the patient.

Conventional monitoring and diagnostic equipment is structured in such a way that one or several electrode(s) is/are mounted on the patient, which tap the respective signals (predominantly potential and impedance values) and transmit such signals via cables to amplifier units. Normally, separate electrodes are used for each measurement parameter.

Especially in EKG and EEG examinations, many cables are suspended on the patient, connecting the EKG/EEG-electrodes with the evaluator units, which process and record the signals. Such cables obstruct the patient and highly limit his or her

freedom of movement, and, therefore, are only conditionally suitable especially for carrying out examinations at stress (e.g. EKG's at stress). In addition, due to the stiffness of the cables and the lever forces connected therewith, the cables become easily detached particularly when the patient moves. Furthermore, in connection with infants, there is the risk that they may play with the cables and detach the glued-on electrodes.

The electrode cables are especially troublesome in connection with home or hospital monitoring of infants. The removal and reattachment of the electrodes is troublesome especially when garments are changed frequently (e.g. during the changing of diapers).

Furthermore, in complicated examinations with a great number of measured quantities such as, for example, in the polysomnography in connection with infants, problems arise on account of the fact that many relatively large electrodes have to be attached to the patient. Moreover, it is necessary in this connection to take into account the psychic stress of the patient, who is connected to an electrical device via a great number of cables. Such psychic stress may have a bearing on both the physical stressability and the physiological characteristic lines.

The above-described methods are high in expenditure, user-unfriendly, and under certain circumstances may require certain medical expertise , for example as far as the arrangement of all sorts of different electrodes is concerned. They are consequently only conditionally suitable especially for use at home, for example for the long-term monitoring of infants. In addition, there is the increased risk of falsified data and alarm malfunction because due to the simple electrode structure, it is not possible to make a distinction between medical abnormalities and technical defects (e.g. detached electrodes).

Therefore, there is need for a nonelectric connection between the electrodes connected to the patient and the equipment. Furthermore, due to the galvanic separation of the electrodes from the evaluation station, the safety of the patient is assured as well.

Telemetry systems for biosignals, in connection with which the EKG- or EEG-data tapped on the patient are transmitted via electromagnetic waves (preferably in the infrared range), are described, for example in "Biotelemetrie IX" (publishers: H.P. Kimmich and M.R. Neumann, 1987, pp 55-58). The data are transmitted in this connection in the one-way mode from the electrodes to the output unit, i.e., without (error) feedback from the receiver to the emitter. A particular drawback in this

connection is that the measured values are transmitted as an analog signal, which means they are relatively susceptible to interference, for example with respect to the 50Hz-ripple and its harmonics.

A further development for telemetric EKG-measurements is described in laid-open patent specification WO 90/08501, where for achieving a higher transmission rate and data safety, the the recorded signals are digitalized, coded (preferably according to the Manchester code, or as FSK [frequency shift keying]), and then transmitted electromagnetically or by light wave conductor.

In connection with said telemetric method, the signals of the individual electrodes attached to the body are transmitted via cable to an additional emitter unit, which is separately attached to the body, and transmitted from there by radio or light wave conductor to the evaluator station. However, the above-mentioned methods have the drawback that the emitter unit is supplied with current via batteries. The batteries have to assure not only the power supply for the data recording and data processing, but also for the data transmission via radio transmission. Therefore, the batteries have to be replaced frequently, which is connected with drawbacks especially in long-term monitoring. Since the emitter units are relatively large, said methods again limit the freedom of movement of

the patient. No details are specified in the above-mentioned references with respect to the structure of the electrodes used for the signal acquisition.

Measuring probes with HF-energy supply are known, for example from the references DE-OS 32 19 558, US-PS 4,075,632, and WO 92/07505. However, the fields of application of said measuring probes are almost exclusively aimed at the identification of objects, and are implanted for said purpose on the animal or human body. Furthermore, the structure of said device is not suitable for the medical signal acquisition as well as for transmitting such signals, in particular not in connection with a great number of data from one or a plurality of electrode(s), and from a number of patients, if need be. With said methods, the signal transmittion takes place almost exclusively via passive telemetry, whereby the measured data are detected in that the measuring probe carries out a modulation absorption in the HF-field of the evaluator station (ES), such absorption acts back on the ES (indirect transmission of information by inductive coupling). Said procedure, however, is suitable only in connection with extremely small spacings between the emitter and the receiver of only a few centimeters (as it is the case especially in connection with implanted probes), and only in the absence of external interferences. Moreover, in connection with said measuring probes, no provision is made for two-way data transmission, i.e., information is transmitted only from the receiver to the

transmitter, so that errors in the data transmission can not be compensated, or compensated only highly conditionally.

The invention is based on the problem of making available a reliable monitoring and diagnosis equipment with wireless electrodes, which is suitable for both the use at home and for operation in hospitals. In particular, a safe data transmission of the electrodes is to be assured also when a great number of electrodes are operated simultaneously.

Said problem is solved by the characterizing features of patent claim 1. Preferred embodiments and further developments are specified in the dependent claims.

The proposed bidirectional, digital data transmission results in the surprising effect that the data transmission safety is significantly increased. By transmitting redundant information in the data emitted by the electrodes, the evaluator station is capable of recognizing errors and request a renewed transmission of the data. In the presence of excessive transmission problems such as, for example transmission over excessively great distances, or due to obstacles absorbing the high-frequency radiation, the evaluator station is capable also of controlling the data transmission, or to manipulate on its own the data emitted by the electrodes. As control of the data transmission it is possible to consider, for example an adaptation of the

transmitting power of the electrode, or a change of the transmission channel. If the signal transmitted by the electrode is too weak, the evaluator station will transmit to the electrode a command, which increases its transmitting power. However, if the signal transmitted by the electrode is superimposed by other sources of interference, the evaluator station, by changing the channel, is capable of attempting securing a flawless and interference-free transmission. Alternatively, the evaluator station can also cause the electrode to change the data format for the transmission, for example in order to increase the redundant information in the data flow. Due to the increased redundancy, transmission errors can be detected and corrected more easily. In this way, safe data transkissions are possible even with the poorest transmission qualities. Said measure opens in a surprisingly simple way the possibility of reducing the transmission power of the electrode to a considerable extent. This reduces the energy requirement of the electrodes, so that the latter can be used uninterruptedly over longer periods of time. Due to the reduced transmitting power is is possible also to exclude possible biological stresses caused by the electromagnetic waves. Another advantage of the bidirectional digital data transmission lies in the possibility of transmitting test codes in order to filter out external interferences such as, for example, refraction or scatter from the transmission current. In this way, it is possible also to reconstruct falsely transmitted data. Due to

the safe data transmission between the electrodes and the evaluator station, the device according to the invention is particularly suitable for use at home such as, for example, for monitoring infants even though no technically trained personnel is available there, as a rule. When used in hospitals, for example for monitoring in intensive care, the device according to the invention offers the special advantage that very many electrodes can be operated at the same time without interferences in one and the same room. Mutual influencing of the electrodes is excluded a priori. In particular, it is possible to program standard electrodes with a great number of sensors via the evaluator station in such a way that such electrodes can be used for special applications, i.e., for special application cases.

The electrodes can be supplied with current by an evaluator station (ES) by means of high-frequency energy transmission (especially in the radio frequency (RF) range). The antennas or optic detectors (e.g. semiconductor diodes) of the electrodes absorb in this connection the high-frequency field (HF-field) radiated by the evaluator station, the latter being arranged spaced from said electrodes. By means of the power supply unit arranged in the electrode, which unit converts (rectifies the HF-radiation and stores it, if need be, then supply voltage is then generated for the electrodes.

The device according to the invention can be designed also in such a way that the power supply unit of the electrodes is realized by additional integrated, miniaturized accumulators. A replacement of weak or empty accumulators is not required in connection with the device of the invention because the accumulators are recharged by the high-frequency field radiated by the e valuator station. Charging of the accumulators can be carried out also only temporarily, for example at points in time at which the electrodes are not in use, i.e., outside of the recording of measured values. In this case, the energy for the charging can be transmitted via resonance coupling, for example by means of inductive coupling. Since the accumulators do not have to be replaced, they also can be encapsulated in the electrodes.

Furthermore, it is possible particularly in connection with long-term monitoring to first supply the electrodes with current through the accumulator, and then later - if necessary - supply the electrodes, for example if the accumulators are weak, with current via the emitted HF-frequency field of the evaluator station. In this way, a possible biological stressing of the body by the high-frequency radiation acting on it can be excluded or minimized.

Frequency generation units generate in the electrodes or in the evaluator station the required oscillator frequencies

for the emitter units as well as receiving units. Preferably, the frequency generation unit comprises one or a plurality of PLL (phase-locked loop) or FLL (frequency-locked-loop) synthesizers, which generate the various frequencies. The transmission frequencies for the (data) transmission may basically extend from the 100 kHz range (long wave) to the 10^{15} Hz-range (optical frequencies). For small electrode dimensions, high bit transmission rates and short transmission distances, transmission frequencies in the UHF range, microwave range and above ($\geq$10 MHz) however, are particularly suitable.

It is advantageous for the device according to the invention if micro-structured sensors such as semiconductor sensors or thin-layer sensors are used for the signal detection or signal recording. Semiconductor sensors are characterized by their small size, their sensitivity, their high integration capability, and their low current consumption. Imp rtant are particularly sensors which are based on the (field effect) transistor (e.g. Si- MOS-FET), the diode or the capacitor principle. In this way, it is possible to realize a great number of sensors such as, for example, bio- or ion-sensitive sensors (ISFET), acceleration, pressure, voltage, impedance, current, temperature, as well as radiation sensors.

By using semiconductor components as sensors with integrated signal processing, transmitting/receiving (tranceiver) and, if

need be, evaluator units, individual circuit arrangements with a number of sensors can be integrated in a chip with edge lengths of less than 10 mm and heights of under 0.5 mm. In this way, the number of electrodes can be reduced, on the one hand, and additional electric components - which are attached to the body and which limit the freedom of movement - can be omitted. Since the distance of transmission from the electrodes to the evaluator station normally amounts to only a few meters (order of magnitude: 1 to 10 m), the energy supply or transmitting power of the electrodes comes, in the ideal case, to only fractions of mW, which means it is completely harmless, medically speaking. The use of miniature batteries (e.g. button cells) is consequently suitable for the energy supply as well, especially for short transmission distances. For this purpose, the TDMA-process is particularly advantageous because the electrodes transmit only at certain time intervals, which means that energy can be saved.

Another feature of the device according to the invention lies in the arrangement of the antenna. The latter is preferably completely (or at least partly) arranged in the electrode covering or electrode diaphragm consisting of, for example flexible plastic. If the electrode is designed in the form of a bracelet, the bracelet can be used as the antenna as well. The antenna can be realized in all sorts of ways, for example as a dipole, lagarithmic-periodic, dielectric, strip conduction or reflector antenna. Preferably, the antenna consists of one

or a plurality of conductive wires or strips, which are arranged in a spiral form (spiral antenna or also helical antenna). In this way, the antenna can be designed with a relati elt large surface area, which requires lower transmission outouts for the data transmission and HF-supply. In particular, it is possible in the radio transmission to use frequency-selective antennas for separating the transmission and receiving bands, and polarization-sensitive antennas in connection with directional transmission. Polarization-sensitive antennas consist of, for example thin metal strips arranged in parallel on an insulating carrier material. Such a structure is insensitive to or permeable to electromagnetic waves with vertical polarization; wa es with parallel polarization are reflected or absorbed depending on the design. It is possible to obtain in this way, for example good cross polarization decoupling in connection with linear polarization.

It is possible, furthermore, to integrate the antenna, for example in the frame of the chip, whereby the antenna is preferably realized by means of the thin-layer technology.

The antenna of the electrodes serves both for transmitting the electrode data and for receiving the control data transmitted by the evaluator station, as well as for receiving, if need be, the high-frequency energy (for the energy supply), i.e., basically,

only one transmitting and receiving antenna is required.

In particular, directional couplers can be arranged on the transmitter outputs of the electrodes and/or the evaluator station, which couplers measure the radiated or reflected (radio transmission) output. Any damage to the antenna (or also any faulty adaptation) thus can be registered, because it is expressed by increased reflection values.

It is possible to carry out the high-frequency energy supply and the data transmission on different frequencies (e.g. data transmission in the IR-range by means of transmitting and receiving semiconductor diodes in the electrodes and evaluator station; energy transmission in the microwave range via the antennas). In particular, it is possible also to transmit sensor data to be transmitted and also electrode control as well as control data from the evaluator station to the electrodes, in each case on different carrier frequencies or at differents points in time.

Preferably, the frequency modulation and/or phase modulation is used for the data transmission in order to exclude excessively long zero series, as they may be present in connection with amplitude modulation. With pure HF-supply of the electrodes, (i.e., without the use of accumulators), transmission of the electrode control and transmission control data to the electrodes can take place, for example by modulating the HF-field.

Furthermore, it has to be taken into account that the radio signal power of the transmitted data is subjected in the receiver to certain variations, as may be the supply voltage of the electrodes (for example if the electrodes are exclusively supplied with energy by the high-frequency field (HF) of the evaluator station. This is mainly the case when the patient moves or turns, thereby changing the spacing between the electrodes and the evaluator station. Also, a certain attenuation and scattering of the signals has to be taken into account, among other things, especially in long-term monitoring (for example in the monitoring of infants or patients in intensive care units), because these measurements are then frequently carried out on dressed patients and in the bed (under a blanket). Therefore, a further development of the invention consists in arranging in the evaluator station a control unit for the transmission output. With said control unit, the evaluator unit determines and controls the transmission output received from the individual electrodes, and, if need be, controls its own transmission output accordingly. If, in the evaluator station, the electrode field intensity falls short of a preset lower threshold value, the evaluator station controls the relevant electrode fror increasing the transmission output. Preferably, the procedure followed is such that maximum values presettable for the electrode transmission output are not exceeded. For this purpose, the electrode transmits its transmission output to the evaluator station.

For controlling the transmission output of the evaluator station, the electrode contains a reference element for measuring the transmission output received. Said transmission output is then transmitted back to the evaluator station, which then controls its own transmission output accordingly.

It is assured in this way that the transmission output of the electrodes and of the evaluator station (including, if necessary, the HF-energy supply) is adapted in each case in such a way that the signal level will not fall short of or exceed certain lower and upper limits in the receiver and in the transmitter. The radiated transmission output is always adjusted by such control processes to the minimum required at the given time in order to receive data with adequate quality, or to optimally operate the electronic units of the electrodes. The transmission output can be adjusted step by step or continuously. This provides the evaluator station with the capability, among other things, to detect whether a signal change is caused by variations in the supply voltage, in the transmission output (with changes in distance), or by a change in the sensor output signal, which is important, for example in connection with amplitude modulation.

Alternatively, instead of the transmission output, the control unit can also control the redundance in the data flow if the bit error rate exceeds a preset threshold value.

A further development also consists in arranging in the electrodes a shutoff unit. When a preset maximum value for the required transmitting output of an electrode (and also of the evaluator unit, if need be) is exceeded, the respective electrode is temporarily automatically deactivated by means of the shutoff unit. the data transmission or recording of the measured values is temporarily interrupted in this way. The evaluator unit then adjusts itself only to the remaining electrodes and may emit an alarm signal depending on the adjustment. The required transmission outputs may be determined, for example by the control unit or by the reference elements in the respective electrodes. Said procedure can be particularly desirable when an infant, during monitoring, is turning, for example from the back to the belly and comes to rest on one or several electrodes. A possible biological stress due to HF-radiation is excluded in this way. The temporary shutoff of electrodes basically can be controlled also by integrated position and/or inclination sensors.

The device according to the invention permits the patient to move freely during the recording of the measured values because such patient is no longer connected to an evaluator station via troublesome cables. When batteries or accumulators are used, such patient may even leave the room for a certain amount of time, especially if the individual electrodes have a data memory. Especially in hospitals, the mobility of the patient can be increased further if the evaluator station(s)

comprise a plurality of global transmission or receiving antennas (arranged, for example, in different rooms and hallways). Advantages of the device according to the invention are seen also in the field of emergency medicine. A victim of an accident can be fitted with the electrodes already at the site of the accident, and their signals are then continuously transmitted to evaluator stations (ES), first to the ES in the ambulance and then to any desired ES in the hospital. The correct code for the electrodes or set of electrodes can be transmitted to the evaluator station in the hospital, for example by means of chip cards or magnetic plug-in cards.

By equipping the evaluator station with an accumulator, infant monitoring can be carried out also "on the road", for example in the baby carriage or while driving in an automobile, especially if such station has a removable monitoring module.

For monitoring patients, it is particularly possible that only a limited number of electrodes connected to the patient receives sensor data and transmits same to the evaluator station. If irregularities or abnormalities occur, the evaluator station can then connect additional electrodes or sensors by deactivating the shutoff unit.

Furthermore, the energy consumption of switched-off electrodes can be reduced in that such electrodes are capable of receiving (for an activation by the ES) and/or measuring (for example for

the integrated (position) sensors) only at certain time intervals.

An additional feature of the invention consists in that identification units can be arrang3d in the electrodes. By allocating certain identification coees - patient code (for a set of electrodes) as well as electrode or sensor code - the evaluator station is then capable of simultaneously supplying several patients in a room, such patients each having a great number of various electrodes, and to evaluate the data and to allocate electrodes or sensors to the respective patients. This is realized in a way such that the electrode or the identification unit has a control logic, as well as a memory for storing the identification codes. The identification unit of the electrodes is preferably programmed by high-frequency radio transmission of control characters and of the respective identification code from the programming unit of the evaluator station to the respective electrodes. A further development comprises the arrangement of (pressure) switches in the electrodes as programming lockouts, particularly for preventing unintensional reprogramming.

A preferred further development of the device according to the invention particularly for long-term monitoring (for example for monitoring infants) is designed in such a way that the electrodes are already equipped with an evaluator unit (with memory). The data transmission can then take place

from the electrodes to the evaluator station temporarily (for example by packets) and/or already processed, if need be (following the reduction of redundant information), or, if necessary, only in the event of irregularities, or when medical abnormalities occur. Irregularities and abnormalities are detected, for example in that the signals are outside certain preset tolerance limits, or in that they deviate more strongly from the values of preceding measurements, which are stored in the (intermediate) memory. The tolerance limits are preferably transmitted by the evaluator station to the electrode and stored in the latter.

The evaluator station (and also the electrodes, if need be) preferably contain(s) a control unit for the various functional units. In the presence of malfunctions (for example: connection to the electrode is defective), the evaluator station can then emit a sound and/or visual warning signal. In addition, it is possible to duplicate critical or important components of the evaluator station (and/or of the electrodes), or to have them present as multiple units. Possible malfunctions can be reduced in this way. Furthermore, the evaluator station and/or the electrodes can be provided with protective devices, for example for preventing antenna overvoltages.

A preferred embodiment consists in the arrangement of control sensors in the electrodes for error detection. A possible

error cause, for example, consists in that a sensor no longer receives any measuring signals, or falsified measuring signals because the electrode has become detached from the skin. Temperature, impedance (measurement of the transient resistance) or spacing sensors are suitable for the control. In this way. a malfunction of the electrodes can be distinguished from possible medical abnormalities or irregularities and thus assure a correct recording of the data, or prevent error alarms (especially in connection with home monitoring).

By means of a status unit in connection with the evaluator station it is possible to adjust which electrodes or sensors are to be used for the medical diagnosis or monitoring. In addition the status unit of the evaluator station can additionally assume control functions , for example by automatically detecting (for example by means of the control sensors arranged in the electrodes, or through the reference element, which measures the supply voltage) whether the electrodes are correctly connected to the body at the start of the medical diagnosis or monitoring. Alternatively or additionally, the electrodes can be equipped with an ON/OFF switch for the activation.

Ideally, all electronic components of the electrodes such as the sensor unit, the sensor control unit, the energy supply unit (except for the accumulator) etc. are designed as integrated circuits and realized on one single chip (electrode chip). In particular, the electrode chips can be realized as

ASIC's (application-specific integrated circuit), or in the form of ASIS's (application-specific intelligent sensor).

ASIC's include, among other things, microprocessors (with user programs in the program memory), circuits with programmable wiring (for example cutting through conducting paths by burning, or through application-specific manufacture of the last mask), and (gate, transistor) arrays. Array circuits represent chips manufactured in standardized ways, whose individual components (e.g. sensors, operation amplifiers, transistors, diodes, etc.) are not connected, and thus unwired. The individual elements are arranged in matrix-form in rows or columns, whereby intermediate spaces are left clear for the wiring. The connections of the individual elements in one or several metallization planes are produced according to the requirements. By using more modern C-MOS technologies (e.g. 0.1 µm technology), the structural dimensions can be highly reduced and the current consumption of the semiconductor components can be kept low. Particularly in connection with ASIS's on a wafer (preferably silicon or GaAs), the chips with the elementary sensors and suitable electronic circuit structures for the control electronics are manufactured with microelectric process steps (for example thermal oxidation, diffusion, ion implantation, metallization, passivation), as well as possibly processes of micromechanics, thin-layer, or thick-layer technology. The individual chips are subsequently finished in the metallization plane depending on the application.

The electrode chips designed as type ASIS or ASICS thus offer the advantage of a rational semiconductor manufacture in spite of varied and different application specifications.

Preferably, the electronic components of the electrodes and evaluator station are realized by means of digital circuit technology. The digital circuit technology satisfies in an ideal way the requirements with respect to integration capability, stability and programmability. Ideally, the evaluator unit of the evaluator station (ES) and/or of the electrodes, as well as the sensor control and transmission control and frequency generation units are realized as microprocessors. However, for the determination of high transmission frequencies, it is necessary the design the receiving and transmitting units in part based on the analog technology.

For reducing the chip size further, preferably the two-side technology or the 3D-integration is used. With the two-side technology, the front and back sides of the chips are used for integrating the individual semiconductor components. It is possible, for example, to arrange the individual elementary sensors in the back side of the chips, and the signal processing and transmitting/receiving units, as well as the evaluating and storing units, if necessary, in the front side of the chips. The electrode chip may be designed also based on the hybrid technology, among others. In connection with the latter, the component is divided in different units such as, for example

in a sensor assembly, tranceiver assembly, etc.

Preferred embodiments of the (bio)sensors are discussed in the following in greater detail. Fpr reducing the number of electrodes, preferably several sensors are arranged in one electrode.

The biophysical recording of measured values is carried out, on the one hand, by means of semiconductor sensors, which are based on the transistor (field effect or bipolar type), diode or capacitor principle. Examples of such sensors are:

* The ISFET, which is structured similar to the MIS-field effect transistor; the metallic gate electrode (control electrode) is, with the ISFET, replaced by an ion-sensitive diaphragm. As diaphragm materials of a sensitive nature, use if made, for example of the following materials: SiO_xN_y, Si_3N_4, Al_2O_3, Ta_2O_5, ZrO_2, AgCl, AgBr, and various polymers, as well as biochemically active materials (enzymes).

* The MOS gas sensor with (catalytic) metal gate electrode (e.g. palladium, platinum) reacts to hydrogen and, with geometrically structured gate electrodes, to other gases (transverse sensitivity). By using integrated (porous) filter layers it is possible to influence the cross sensitivity and thus the response behavior. With circuits of MOS gas sensors that are connected in parallel or in series it is possible to obtain

distinct quality improvements and a superior response behavior.

* The barrier-layer temperature sensor, in which the temperature dependency of p-n junctions in semiconductor components is used for measuring the temperature. Preferably, for this purpose, two identical transistors are operated in a differentiating network at the same temperature with different collector currents (measuring accuracy about 0.1°C).

* Photodiodes, especially the p-i-n photodiode, as well as phototransistors.

One alternative consists in realizing the sensors (and circuits) by means of thin-layer technology by applying thin inorganic or organic layers (films) to an insulating carrier material (substrate). The measuring principle of such sensors is based on the change in the electrical properties (e.g. electric resistance) of the thin layer under the influence of the external quantity to be measured. The application of this technology permits integrating a great number of elementary sensors with circuits on one chip, e.g. based on the hybrid technology. In connection with the thin-layer technology, vacuum processes are used for producing (by vapor deposition, application by atomization, or chemical deposition) thin metal, insulator or semiconductor layers on ceramic material, glass or plastic substrates, with layer thicknesses of less than 1 µm.

As layer materials, preferably metal layers (e.g. aluminum, chromium) are used for conductors (conductor paths) and electrode pins, and for resistor layers perferably, for example, NiCr and tantalum, and for insulating layers preferably SiO_2, Si_3N_4, AlAs (for the GaAs-technology), and Ta_2O_5. The following can be produced as sensors with application of the thin-layer technology:

* Temperature-dependent resistor layers made, for example of platinum, gold, nickel, copper and iridium (resistance thermometer) and possibly thermoelements (Seebeck effect);

* light-sensitive layers, for example made of CdS, PbSe, Si, etc.;

* moisture-sensitive layers: the sensor contains electrodes engaging each other in a toothed way like a comb, such mating electrodes being protected against the moisture-sensitive layer/ layer sequence. For realizing the moisture-sensitive layer it is possible to use materials such as polymeric plastics, metal oxides, and porous ceramic materials;

* gas-sensitive layers such as, for example, semiconducting metal oxide layers (SnO_2, Fe_2O_3), particularly for detecting CO_2;

* magnetoresistive layers such as, for example Ni-Fe-alloys, as well as

* pressure-sensitive resistance layers such as strain gauges consisting of metallic film resistors (e.g. NiCr, CrSi and TaNi layers or foils, or of semiconductor layers. The pressure is measured in this connection through a change in the electric resistance; with metal strain gauges through a deformation; and with the more sensitive semiconductor-type strain gauges through the piezoresistive effect.

The thin-layer sensors particularly include also the SSW-sensors (sound surface wave). SSW-sensors belong to the SSW-components whose function is based on the stimulation of mechanical vibrations on the surface of piezoelectric solids or layer structures when an electric voltage is applied to a metallic converter (IDC = interdigital converter) with mating finger structures. The SSW-sensor, when converting the sound wave into an electric signal, makes use of the electroresistive effect, which represents the reversal of the piezoelectric effect. The surface wave propagating between two IDC's is freely accessible and subjected to different biophysical quantities. Its propagation property (propagation rate and attenuation) is dependent upon, for example the gas concentration (by means of selectively absorbing layers), the moisture and the temperature of the surrounding medium directly on the surface of the substrate. With the help of these sensors it is possible, therefore, to realize different biophysical sensors, particularly gas sensors, temperature sensors, and moisture sensors. The great advantage of the SSW-sensors is the direct conversion of the

easured biophysical quantity into a frequency and the frequency-analogous interface connected therewith. This results in relatively good immunity to interference, high reliability, as well as simple digitalization, because a simple frequency counter can be used instead of a analog-to-digital converter.

Since the substrate can be selected largely independently of the type of sensor layer used, the substrate and the sensor layer can be optimized independently of one another with respect to their specific properties, and a complex sensor system can be realized in this way. The thin-layer sensor technology and the semiconductor sensor technology are consequently fully process-compatible.

Basically, the thick-layer technology can be used for the manufacture of the electrode chips or of the sensors as well, for example for realizing the structure of superset or hybrid-integrated circuits.

For monitoring the breathing, acceleration sensors (or also motion sensors) consisting of one or a plurality of semiconductor components with inert mass are used, on the one hand, by measuring the up and down motion of the thoracic cage or of the abdomen. These sensors are considerably more sensitive and reliable than the conventional "air cushion electrodes", and, furthermore, integratable.

The breathing can be controlled also via a spacing sensor, which is integrated in an electrode arranged within the abdominal region. The spacing between the electrode and the evaluator station, which varies with the respiratory activity, can be determined in this connection, for example based on the difference in running time of the signals between the electrode and the evaluator station. The antenna of the evaluator station is, for this purpose, preferably mounted directly above the sleeping patient or the infant to be monitored. For control purposes it is possible to use additional spacing sensors, which are integrated in reference electrodes (mounted in sites that do not sensitively react to breathing motions such as, for example, on the head, arm, leg, etc), or in other electrodes. It is possible in this way to distinguish movements of the entire body from breathing motions.

Alternatives to monitoring of the breathing by means of acceleration or spacing sensors consist in the use of temperature, gas (CO_2 or O_2) or air humidity sensors, which are attached near the mouth and nose (preferably between the two).

The oxygen can be measured, for example by means of a Clark-cell. For this purpose, a micromechanical, spiral-shaped groove is etched, for example in an Si-chip or Si-wafer. A silver anode is produced by vapor deposition on the bottom of the groove, and a silver cathode between the grooves. The groove

is filled with a polymer, which is impregnated with common salt solution, and finally covered with the diaphragm, the latter being permeable to oxygen. When a dc voltage (abt. 0.8 V) is applied to the electrodes, an electrolyse reaction occurs, which supplies a current proportional to the oxygen concentration.

CO_2 is detected, for example by means of an ISFET, whose ion-sensitive diaphragm contains a water-impregnated layer. In this connection, the CO_2 diffusing into the water-impregnated layer leads to a chemical reaction with pH-shift.

The impedance or potential measurement, for example for the EKG or EEG signals, is carried out by means of measurement amplifiers consisting of difference operation amplifiers (with installed filters). Basically, also 3 and more tapping points (hereinafter referred to as electrode pins) can be arranged in one electrode. One electrode pin can be used in this connection for the reference value.

For measuring potential differences or impedances, a galvanic connection has to be present between the individual tapping points. Therefore, without a galvanic connection, it is possible only to determine the impedance values between the individual electrode pins in an electrode. Since the spacing between such electrode pins can be selected relatively small (up to about 1 cm; ideally 3 to 5 cm), it is possible in this way to monitor

action voltages in small regions because the transmission takes place only over a small distance, which permits more sensitive measurements. In order to determine impedances or action potentials over greater distances, i.e., for example between two electrodes, such electrodes are galvanically connected with each other by means of a plug connection (for this purpose, the galvanically coupled electrodes have to be equipped only with the required electrode pins and, if need be, measurement amplifiers, but must not have their own transmitting, receiving, energy supply units, etc.).

Integrating two or more electrode pins in one electrode considerably simplifies the handling. In addition, the arrangement, due to the integration of control sensors, permits a significantly better error diagnosis, for example in the event of incorrect mounting. Preferably, the sensor has an oblong shape (with two electrode pins) or the shape of a cloverleaf (with 3 or 4 electrode pins), which assures that with a small electrode surface, the spacing between the individual electrode pins or tapping points will not be too small, which would lead to measuring errors especially at high skin/electrode transition resistance.

The transition from the ion conduction of the body to the electrode line of the (EKG/EEG) lead connections takes place at the electric transition between the (EKG/EEG) electrode pins

and the skin of the patient. This generates a galvanoelectric dc voltage which, due to irregularities of the skin, can assume different values, and which effects a galvanoelectric dc voltage between two (EKG/EEG) electrode pins. Said voltage has to be suppressed in the processing of the signal because it is significantly higher than the useful signal. Furthermore, as little current as possible should flow via the (EKG/EEG) electrode pins because such flow changes the chemical composition of the skin and causes polarization voltages that may vary highly in terms of time. Therefore, the input currents have to be low and the input amplifier has to have a high input impedance These cpnditions are ideally satisfied by operation amplifiers or measurement amplifiers based on the former.

It is notable in connection with impedance and potential measurements that conventional multiplexers are not capable of well-processing signals in the mV-range with a high dc voltage component. Therefore, for processing such signals, the dc voltage is suppressed by means of filters. Multiplexing of the sensor signals then takes place following the input amplification. Measuring the action potential by means of measurement amplifiers has the advantage that suppression of the dc voltage by filters (high-pass or bandpass filters) can be effected already directly in the measurement amplifier.

For temperature measurements, it is possible to use - in addition to the aforementioned sensors - also propagation resistance

sensors, polysilicon temperature sensors (preferably based on the thin-layer technology), and basically also thermoelements. A contactless temperature measurement of the surface of the skin is basically possible as well; the temperature is detected, for example via the emitted heat radiation (infrared, remote infrared) of the body. With propagation resistance sensors, which have a high long-term stability, the specific resistance of semiconductors is measured according to the single-tip method. The propagation resistor preferably consists of a monocrystalline Si-crystal (e.g. with a lateral edge length l of about 0.5 mm and a thickness h of 0.2 mm) and has on the top side an etched contact hole with a diameter d ($\ll$ h, l) of about 20 µm, from which a contact is produced by a strong doping (n^+) and application of metallization layers. The resistance R between a rearward metal contact and the metallization contact then only is still dependent upon the temperature-dependent specific semiconductor resistance p of the (n-) doped silicon ($R = \frac{p}{2d}$).

Position sensors for the determination of the (sleeping) position of the patient (for example belly, back or side position) are preferably realized by magnetic field sensors. Magnetic field sensors contain, for example a Hall element consisting of a (thin, long stretched-out) metal platelet, or a silicon or GaAs semiconductor platelet. For the determination of the position, a constant current is impressed into the Hall element, and the

Hall voltage is evaluated as a function of the magnetic flow or the vertical component of the outer magnetic field of the earth. By arranging three Hall elements in the sensor or electrode, such elements being arranged vertically relative to each other, it is then possible to determine the exact position (belly, back or side position) of the patient.

An alternative is the use of inclination sensors, which is many cases operate according to the capacitive measuring principle. Capacitive inclination sensors consist of a microstructured measuring cell, which is filled with liquid and an inert gas. In this connection, the two plates of a capacitor (or of a plurality of capacitors) are more or less covered by the liquid dielectric depending on the inclination. Turning of the sensor results in a change in capacity that is proportional to the angle. Basically, the position can be determined via micromechanical sensors as well.

Control sensors are used especially for avoiding false alarms or falsified measured values. Such sensors can be realized, for example in the form of spacing sensors (ultrasound or radiation emitters and transmitters for determining the distance between the electrode and the skin), impedance sensors (measurement of the transition resistance between the electrode and the skin), temperature sensors (sensor measures the temperature of $\geq$36°C if the electrode is suitably attached), moisture sensors, or reference sensors.

For the determination of the value of oxygen saturation (O_2) in the blood, transmission or reflection measurements are carried out. Preferably IR radiation emitters and receivers (diodes) are used for these measurements. IR emitters and receivers are arranged in this connection on the same or opposite sides of parts of the body (fingers, toes, palm or back of the hands) with high blood circulation (also on thin parts in connection with transition measurements).

Moisture sensors are preferably realized in the form of impedance sensors (operation amplifiers) or ISFET's, which determine the sweat content or the pH (ion concentration of NaCl) on the skin.

Usefully, the evaluator station contains a calibration unit (with memory) for the sensors, in particular for the temperature, gas, ion-sensitive and Hall sensors. Basically, such a calibration unit can be arranged in the respective electrodes as well.

The radio transmission of the digitalized and coded sensor data is effected by the digital modulation (rekeying) of a sinusiodal carrier signal, in connection with which shifting takes place between discrete (e.g. two or four) wave shapes, or by means of discrete pulse modulation methods. The modulation or demodulation can take place directly in this connection (i.e. at the transmission frequency), or also indirectly (with an intermediate frequency), in which case, however, changing(via mixers) to the transmission frequency is necessary.

In connection with the digital carrier frequency technology, either the amplitude, preferably, however, the frequency (FSK = frequency shift keying), or the phase (PSK) - as particularly with the GMSK = Gaussian minimum shift keying - is varied (modulated),or a combination from the three methods is used.

For the discrete pulse modulation (basic band transmission), particularly the PCM-method (pulse code modulation) or the DM-(delta modulation) method is considered. These methods are preferably used for the optical transmission of the data (e.g. in the IR-range by means of semiconductor diodes). In this connection, by scanning with quantized amplitudes, a change of analog (sensor) signals into coded digital signals takes place, namely mostly in sequences of binary pulses with the values 0 or 1. Possible are 8 - for example with companding -, but also 10 or higher-digit (linear) code words are possible with one or several parity bits. Coding is carried out, for example according to the Manchester-method.

For superior exploitation of the transmission channels, i.e., in order to be able to transmit the sensor data and the data of the evaluator station independently and simultaneously, the individual signals of the electrodes or sensors and of the evaluator station are preferably additionally processed prior to the transmission by a multiplexer (line transmission). Among the multiplex methods, especially the TDMA (time division multiple

access) process, the FDMA (frequency division MA) method, and the CDMA (code division MA) method are of interest.

With the TDMA-method, message signals are transmitted in blocks of data in a time-interleaved arrangement in a cyclic sequence. With the PCM, for example, this is possible because the pulses have a short duration, so that scanning samples of other input signals can be inserted in the intermediate spaces. With the FDMA method, the transmission medium is divided in N identically sized frequency bands (e.g. with N or N/2 transmitters). By modulation with staggered carrier frequencies, the basic bands of the primary signals are shifted in this way to higher frequency positions, in a way such that they come to rest next to each other on the frequency scale.

With the CDMA-method, a distinction can be made in this connection between the "frequency hopping" and the "direct-frequency" coding. With the frequency hopping, several frequency (part) bands are available for the transmission. The message to be transmitted is divided in packets of the same length, which are transmitted one after the other on different part bands. In this way, a noise pulse generator cannot simultaneously interfere with all frequencies, so that only a few packets are disturbed by such a generator. Due to sufficiently high redundancy, the entire message will then reach the receiver with a good quality in spite of the interference. With direct sequence or also pseudo-noise coding, the message is highly stretched by bits in terms of time

before it is transmitted, and modulated with a pseudo-random binary sequence. A receiver knowing the binary sequence can extract the useful signal again from the pseudo-noise. The separation of the signals is assured by the selection of orthogonal code sequences. This permits, on the one hand, a parallel transmission of different messages on one band; on the other hand, this method is relatively insensitive to wideband and narrowband interferences.

The space-division multiplex method offers another possibility for data transmission. In this case, the evaluator station is equipped with a plurality of transmitting/receiving antennas, which each are directed at different patients to be monitored. Said method, furthermore, has the advantage that the antennas can be arranged relatively close to the patient (e.g. directly above the patient's bed), which permits reducing the transmission power. Especially in connection with directional antennas, the antenna can be equipped with an additional control unit and a driving motor, such unit and motor aligning or adjusting the antenna in such a way that the transmitting/receiving adjustment is always optimal. This method basically can be used also in connection with a great number of electrodes attached to the patient. Especially with very large systems, for example in hospitals, several evaluator stations each having several antennas can be interlinked via cables or radio

transmission. The individual sets of electrodes will always respond to the most suitable evaluator station or antenna (e.g. to the closest one), and when the patient is moving, will be handed-over to the next ES, if need be (hand-over). For reducing interferences, the individual evaluator stations are preferably operated on different frequency bands.

Depending on the complexity of the data transmission methods, transmission control units are arranged in the electrodes. Preferably the evaluator station has a master transmission control unit and controls the transmission control units of the electrodes via signalizing data (synchronization). In this way, the evaluator station prevents collisions in the data transmission of different electrodes.

So that in the data transmission, the receiver is capable of scanning the received signals at the correct points in time in order to be capable of recognizing the individual bits correctly, a synchronous operation between the transmitter and the receiver is useful and necessary (synchronous data transmission). For this purpose, the evaluator station preferably contains a synchronizing unit which, as the reference cycle clock generator, controls the clock generators of all nodal points of the network, i.e., of the electrodes by means of synchronization characters and/or via a reference timing frequency, for example according to the master slave method, and in this way assures the frequency, clock,

hase and/or frame synchronization (TDMA). In particular, the high frequency (HF) for the energy supply can be used as the reference timing frequency. It is possible also to use the demodulated signal for the clock recovery, among other things.

It is basically possible also that the cycles of the individual electrodes do not correspond with the one of the evaluator station (ES) (asynchronous operation), or slightly deviate from the cycle of the ES within preset limit values (plesiochronous operation). If, for example, one electrode has a sligher higher clock pulse frequency than the evaluator station, the ES may occasionally be incapable to read a bit; reversely, the electrode will occasionally read a bit twice. This error can be compensated, for example through the use of padding methods, i.e., through the use of bits that do not carry any useful information. An alternative consists in that the system accepts an occasional slip. By using slip controls in the receivers it is particularly possible to prevent the system from losing its frame synchronization in spite of slip, for example in that a shift takes place by a whole frame, and not only by one bit width. Therefore, the requirements with respect to synchronization between the electrodes and the evaluator station can be low, comparatively speaking.

Suitable for the transmission is particularly also the subdivision of the signals (to be transmitted) in packets, whereby

each packet is provided with suitable addressing, code protection etc. (packet transmission). One packet comprises, for example start, stop, control and synchronization bits, the address of the transmitter and of the receiver, a test code, if necessary, as well as the useful information.

In the simplest case, the data are transmitted by the simplex method, i.e., from the electrodes to the evaluator station, and without acknowledgement and reception confirmation. However, the half-duplex (in both directions, but not simultaneously) or the full-duplex operation is preferably used for the data transmission. With both of said methods, the evaluator station may both confirm the reception of the data and also transmit command sequences to the individual electrodes.

Basically random-oriented and also reservation methods are available for the channel access. The random-based methods include particularly the ALOHA-, CSMA-(carrier sense multiple access) and CSMA-CD- (CSMA with collision detection) methods, which are not discussed here in greater detail because they are of secondary importance to the device according to the invention. In connection with the reservation methods, the physical channel is divided by a time period (TDMA), a frequency (FDMA), or a code (CDMA). The channel access can take place also priority-oriented, i.e., according to a preset priority stage of the individual electrodes. The fixed allocation of transmission rights is possible only with knowledge of the number of electrodes or electrode sets that

may transmit simultaneously.

For safeguarding the transmission quality it is advantageous, furthermore, to carry out the transmission according to the (code-independent) HDLC-method (high level data link control). In connection with said method, not each block is individually acknowledged after it has been transmitted, but several blocks are transmitted in one direction one after the other. The receiver (e.g. the evaluator station) can insert the acknowledgement in own data blocks, which are transmitted in the reverse direction (e.g. to the respective electrodes).

For reducing transmission errors, additional redundancy can be incorporated in the message sequence to be transmitted (channel coding). Deterministic codes (such as, for example, block codes, recurrent codes) and also stochastic codes can be used in this connection. An error correction unit in the evaluator station and/or in the electrodes will then execute, for example a direct error correction at 1-bit transmission errors (FEC = forward error correction), so that a repeat request for repeating the data transmission can be omitted.

The data to be transmitted can be coded by a secret code for special applications. For this purpose, the signal processing units of the electrodes and of the evaluator station are equipped with coding and decoding units. Said units are preferably arranged in the encoders and decoders, respectively.

For increasing the reliability of the data transmission, training sequence units or equalizers may be arranged especially in the electrodes and/or evaluator station. A training sequence unit in the electrode generates a test code (character sequence), which is specified between the transmitter and the receiver, and transmits said test code to the evaluator station at defined times. The test code also may consist of, for example the identification code of the individual electrodes, or contain said code. With the packet or time-slot operation, the test code is preferably arranged in the center of each packet or time-slot. The equalizer in the evaluator station compares the received test code with the specified one, and determines the algorithm for recovering the transmitted data. In the event of distortions or trouble such as due to multiple reflections, diffraction and interferences due to the absence of sight contact between the receiving antenna of the evaluator station and the electrodes (patient turned away, dressed or under the bed blanket), the receiver can then equalize the transmission. The equalizer and the training sequence unit also may be arranged in the electrodes or the evaluator station alternatively or additionally. The use of test codes is particularly useful if the transmission distances are greater or if the transmission frequencies or bit rates are very high.

A preferred further development consists in the use of nesting/denesting units. For this purpose, individual bits of

a data block are time-interleaved (scrambling) and divided in a number of sub-blocks. Especially in connection with the TDMA-method, such sub-blocks can be divided in different data bursts. On the receiving side, burst errors lead to 1-bit errors of the unscrambled data and may be eliminated by the error correction unit, so that data transmission errors are thus reduced.

Preferred embodiments of the device according to the invention are explained in greater detail in the following by reference to the attached drawings, in which:

Fig. 1 shows a schematic structure of the device according to the invention;

Fig. 2a shows a plan view and cross sectional representation of an electrode with a plurality of sensors according to Fig. 1;

Fig. 2b shows a plan view and cross sectional representation of an alternative electrode with a plurality of sensors;

Fig. 2c shows a plan view and cross sectional representation of another alternative electrode with a plurality of sensors;

Fig. 3 shows an arrangement of the electrodes on the patient;

Fig. 4 shows an electrode for absorption measurements, with a measured curve;

Fig. 5 shows a transcutaneous oxygen ($tcpO_2$) and carbon dioxide ($tcpCO_2$) electrode;

Fig. 6 shows a hand electrode for an infant;

Fig. 7a shows a circuit for measuring the bio-potentials, in particular the EKG and EEG action potentials; and

Fig. 7b shows a circuit for measuring the bio-potentials, in particular the EKG and EEG action potentials.

Fig. 1 shows the basic schematic structure of the device according to the invention. The device contains as components an evaluator station (1), as well as one or a plurality of electrodes (2a to 2f), which are arranged on one (or a number of) patient(s). In the example explained here, the data are to be exchanged between the evaluator station and the various electrodes according to the TDMA-method with PSK-modulation. Without limiting the general idea of the invention, the individual electrodes within a set of electrodes (i.e., for a certain patient), furthermore, are to have the same transmission frequencies, whereby the transmission is to take place in the doublex operation with two separate frequency bands in the 1 GHz-range (with less complex systems, e.g. for the home

monitoring of infants, with a highly limited or specified number of electrodes, the frequency multiplex method can be used as well).

With multiple access in the time multiplex, the and the evaluator station periodically transmit pulse bundles (bursts). For synchronization, the bursts are combined in frames. The transmission times of the pulse bundles (e.g. data bursts) transmitted by the various electrodes are shifted against each other in terms of time in such a way that the bursts are lined up at the input of the various receivers (e.g. of the evaluator station) with as few gaps as possible without, however, overlapping one another. This is achieved, for example in that each electrode transmits its burst in reference to a reference burst, which is transmitted by the evaluator station, and controls and corrects the transmission phase with the help of the reference burst. In particular, in the presence of greater distances, the running time of the signals between the electrode and the evaluator station can be taken into account in connection with the transmission phase of the electrode as well. In addition to the transmitted sensor or useful data, each data burst also contains a preamble consisting of the synchronizing header, the start-of-message identifier of the burst, if necessary sender addresses, and additional system-internal signalizing data, if need be.

The synchronizing header is a preset code sequence permitting a rapid synchronization of the carrier, cycle and frame (additional synchronization can take place via separate synchronization bursts). The start identifiers of the bursts indicate at which point of the header the receiver has synchronized. Dummy bursts are used when no useful data are transmitted. The first access preferably takes place according to random-oriented (e.g. ALOHA) or also according to prioruty-oriented methods.

The evaluator station (1) shown here is equipped with a receiving and transmitting antenna (4a), a receiving/transmitting separating filter (antenna separating filter, frequency separating filter, bridge separating filter) (4), a control unit (4b) - for determining/controlling the transmission power - , a receiving unit (5), a transmitting unit (6), as well as with a data processing or evaluating unit (7) with associated display (8a), printer (8b), storage (8c) and alarm (10) units. Additional components are the frequency generation unit (11) as well as the transmission control unit (7a) with the sequencing control (7b). The evaluator unit (7) contains a status unit (7c), which controls the selection of the patient, of the electrodes, as well as of the sensors contained in the latter. Based on such selection it is determined to which sensor a subsequent command is addressed. For detecting and minimizing transmission errors, pro vision is made in the evaluator station (7) for an error diagnosis and correction unit (7d). The latter uses redundant information in

the transmission in order to be capable of eliminating errors. In order to permit a simple calibration of the sensors (40a ... 49i) of the electrode (2), provision is made for a calibration unit (7e). The electrode is subjected to a fixed standard condition, from which the signals of the sensors (40a ... 40i) to be expected are known. The calibration unit (7e) adjusts internal parameters of the electrode (2) such as, for example amplification factors or offsets, to such an extent that the sensors (40a ... 40i) supply the expected signals. The receiving unit (5) or transmitting unit (6) substantially consists of a signal conversion unit (12-16, and 26-29, respectively), as well as of a signal processing unit (17-20 and 21-25, respectively) (this applies analogously to the electrodes).

The signal conversion unit for the receiving unit (5) contains a high-frequency amplifier (12) with synchronizable bandpass filters (for preselecting the transmission frequency of the individual electrodes), a mixer unit (13), a low-frequency (LF) amplifier with filters (14), as well as a demodulator (15). The mixer unit (13) may, in this connection, comprises a plurality of intermediate-frequency mixing stages (with the respective filter and amplifier stages), and, via one (or several) oscillator(s) in the frequency generator (11)(frequency synthesizer), converts the the high frequency signals received (in the GHz-range) into the basic band (or an intermediate-frequency band). In the demodulator (15), which preferably is a quadratur modulator,

the signals are finally PSK-demodulated, as well as amplified again, if necessary (not shown). A connected equalizer (16) equalizes the signals. The demodulated signals are finally processed by the burst demultiplexer (17), which executes the TDMA-deframing, the deleaving unit (18), as well as the decoding unit (19), and the digital signals are further transmitted to the evaluator unit (7). The decoding unit (19) converts the signals received into binary signals, and executes an error correction. By means of the specific identification codes, which, for example, are stored in the evaluator unit (7) or in a separate identification unit, the individual data can be assigned to the respective patients, electrodes, or sensors. Subsequently, the different electrode data can be assigned to the respective evaluator sub-units by a demultiplexer (20).

The transmitting unit (6) comprises the digital multiplexer (21), the encoding unit (22), a training sequence unit (23), the interleaving unit (24), the burst multiplexer (25) for the TDMA-framing, the (PSK) modulator (26), a low-frequency amplifier (27), the mixer (28), as well as finally the HF-transmission amplifier (29) with built-in bandpasses.

The control unit (7a) serves for controlling the transmission between the evaluator station and the electrodes, as well as for controlling the frequency generation unit (11) and the sequencing control unit (7b). The frequency generation unit (11) especially

comprises also a clock unit, which supplies the various system cycles especially for the evaluator processor (7) and the TDMA frame structure. Said unit particularly serves also for frequency and cycle synchronization of the electrodes with the evaluator station. For this purpose, the carrier frequencies and the system cycle are transmitted to the individual electrodes by the evaluator station via synchronization bursts (the high-frequency field received for the energy supply can be used also directly, for example for transmitting the carrier frequency, among other things).

The frequency generation unit (11) comprises, for example one or a plurality of PLL (phase-locked loop) synthesizers, which generate(s) the various carrier frequencies within the range around 1 GHz. The frequency generation unit (11) particularly supplies the various oscillator frequencies (as well as the carrier frequencies) for the mixers and modulators, and also a reference frequency, from which the individual oscillator frequencies are generated. The reference frequency can be generated in this connection by means of (temperature-compensated) quartz oscillators or synchronizable oscillators.

The evaluator station is adapted to the burst operation via the sequence control (7b), which controls the burst (de)-multiplexers (16, 22), the (de)modulators (15, 26), etc. For the TDMA (de)framing, the data are fed into intermediate

memories (not shown) and read in and read out at the correct points in time at the system bite rate.

For the application of a plurality of electrode sets (with different carrier frequencies), for example for simultaneously monitoring a number of patients, several receiving units (5) and transmitting units (6) are required, or one receiving and transmitting unit with a great number of (de)multiplexers, (de)modulators, amplifiers, bandpasses, etc. for the individual carrier frequencies (not shown here in the drawing).

For other transmission methods such as, for example CDMA-transmission or TDMA with frequency hopping, additional synchronization stages as well as code generators and/or frequency synthesizers for code or frequency rekeying have to be integrated in the receivers and transmitters, i.e., in the evaluator station and the electrodes.

The power supply of the evaluator station can take place in this connection via a mains transformer and/or accumulators (9). Preferably, the evaluator station contains a removable, small portable module (1a) containing the important operational units such as the antenna unit (4a), the transmitting (6) and receiving unit (5), the evaluator (7), the transmission control unit (7a), the frequency generation (11), the accumulator (9), and alarm units (10) (the latter with sound and/or visual warning signals). Thus the device can be used also outside of the home

for monitoring infants, for example during automobile drives or while taking a walk.

The electrodes (2) each contain an energy supply unit (37), the receiving and transmitting antenna (36a), the latter having an antenna separating filter (36) for the transmitting and receiving operations, a transmitting unit (31), a receiving unit (30) (e.g. for synchronization, indication of the transmitting power, protocol transmission, error correction, programming and controlling), a sensor unit (34), as well as a frequency generation unit (35).

The frequency generation unit (35) particularly comprises also a clock unit for the various system cycles. The frequency generation unit (35) supplies the various oscillator frequencies (as well as the carrier frequencies) for the mixers and modulators, and also a reference frequency, from which the individual oscillator frequencies are generated. The reference frequency is preferably generated by means of a VCXO (voltage controlled crystal oscillator) reference generator, which can be retuned in a highly precise way, in order to assure the required frequency accuracy with the evaluator station. For the voltage/frequency conversion it is possible to use, for example a varactor.

The electric signals of the individual elementary sensors (40a-i) are amplified and filtered by the preamplifiers. Preferably,

the sensitive input amplifiers (41a-i), for preventing over-driving, for example due to HF scatter, are equipped with protective devices, for example with a Zener diode circuit for signal limitation (not shown here). The amplified and filtered (equalized) signals are then applied to a high-speed analog multiplexer (42), which is controlled by the sensor control unit (33). The sensor control unit (33) receives the control commands from a storage unit (33a), or directly via radio transmission from the evaluator station (1). For detecting and correcting transmission errors, the electrode (2), too, has an error diagnosis and correction unit (33b), which operates in the same way as with the evaluator station (1). Then, the signals at the output of the analog multiplexer (42) are amplified again sensor-selectively by an amplifier (43), if necessary, and then applied to the analog-to-digital converter (44). By means of the identification unit (45a), the encoding unit (45) converts the analog dignals into the electrode- or sensor-characteristic digital code. The coded electrode signals and the training sequence (test code) of the training sequence unit (46) are then applied to the interleaving unit (47) (the aforementioned equalizer (16) in the receiving unit (5) of the evaluator station (1) uses the training sequence for equalizing the data). The interleaved, coded sensor data are then adapted to the TDMA-framing via the burst multiplexer (48), and, for modulation, fed into the (PSK) modulator unit (49). For amplification and change to the carrier frequency, the signals are applied to

the mixer unit (51) via the low-frequency amplifier (50). The final HF amplifier (power amplifier) (52) with bandpasses amplifies the transmission signals and feeds the latter to the antenna (36a) by way of the transmission/receiving separating filter (36). Preferably, the sequence control (34a) controls the HF amplifier (52) in order to adjust a suitable transmission output.

The receiving unit (30) for receiving the radio and control data of the evaluator station contains the HF amplifier (55) with synchronizable bandpasses, the mixer (56), the low-frequency amplifier (57), the demodulator (58) with the equalizer (59), the burst demultiplexer (60)(for the TDMA deframing), the delacing unit (61), as well as the decoder (62). The amplified digital signals are then transmitted further, for example to the storage unit (33a) or the sensor control unit (33). The sequence control (34a) in the transmission control unit (34) especially controls the interlacing/delacing units (47; 61), the burst (de)multiplexers (48;61), as well as the respective intermediate memories (not shown) for the TDMA-framing or TDMA-deframing.

The transmission control unit (34) is monitored by the evaluator station (1) and, when deviations from should-be values occur (e.g. of the transmitting power), receives correction instructions. The transmission control unit (34) is particularly responsible also for the frequency and cycle

synchronization of the frequency generation unit (35). Preferably, the transmission control units (7a; 34) or the sequence control (7b; 34a), furthermore, contain synchronization stages (not shown in the drawing) which, on the one hand, determine the point of arrival of the bursts, and measure the channel distortion, on the other hand, in order to make the required information available to the equalizer.Said synchronization stages can be arranged also in the receiving units (5; 30). A frequency and cycle synchronization can take place particularly via the test code of the ES.

The HF-field emitted by the evaluator station is converted by the energy supply unit (37) of the electrodes into the supply voltage, and the energy supply unit stores the excess energy in an accumulator (38).

The receivers (5; 30) of the evaluator station (1) and the electrodes (2) may basically be designed in the form of straight-ahead and overlay receivers, and particularly as synchronous and quadratur receivers and Superhet's. The amplification, synchronization and selection means of the respective transmitting and receiving units, which are shown in Fig. 1 in only one box, particularly can be distributed to a number of units/stages. The individual amplifier elements in the receiving units of the evaluator station (1) and/or the electrodes (2) are controlled by an amplification control

unit (AGC = automatic gain control) and monitored by the latter (not shown). The transmitting and receiving units are defined in the present specification in such a way that they contain the modulation and demodulation components.

For a digital design of the receiving units (5; 30), the signals received are converted into digital signals at intermediate frequencies (≪100 MHz), or in the basic band. For this purpose, digital-to-analog converters are integrated either in the mixing (13; 56) or in the demodulation units (15; 58). This applies analogously to the transmitting units (6 and 31) as well. The electrode units and the evaluator station are then controlled by digital microprocessors. Especially the homodyn receiver offers advantages for the monolithic integration of the entire receiver because the selection is shifted there to the basic band.

Figs. 2a and 2b show two typical exemplified embodiments for the design of the electrodes on a scale of about 2:1. Without limiting the basic idea of the invention, the individual electronic components of the electrodes, i.e., the elementary sensors and the sensor control, transmitting/receiving and transmission control units etc. are integrated in one single semiconductor chip.

With the electrodes, the antenna (36a) is designed as a spiral antenna arranged in the flexible electrode covering (71).

On the underside, the antenna (36a) has a reflector (36b), by which the HF power radiated from the antenna (36a) in the direction of the patient is reflected upwardly. Preferably, the spiral antenna is realized with two or four arms; only one arm is shown here for the sake of better clarity. Since radiation in the direction of the body, i.e., radiation from both sides is undesirable, a plane reflector (not shown) is mounted between the antenna and the electrode covering facing the skin, preferably with a spacing $\lambda/4$ (λ = wavelength). This enhances the radiation in the desired direction of transmission; however, this is connected with a reduction of the bandwidth. Another possibility is the projection of the plane spiral antenna onto the surface of the electrode cone (conical spiral antenna).

The electrodes are fastened on the surface of the skin preferably by means of exchangeable adhesive tapes (coated with adhesive on both sides) or adhesive rings.

Some electrode designs can be basically arranged also on materials resting closely to the skin such as, for example, bracelets, pieces of garment, or mattresses, if need be. Important is only that the sensors are in adequately close contact with the body.

Fig. 2a shows a possible arrangement of the individual semiconductor elements such as the elementary sensors (40a to 40i), the sensor unit (32), an evaluator unit (74), the sensor control (33), the transmission control (34), the frequency generation (35) units, as well as the transmitting/receiving (31, 30) and the energy supply (37) units of the electrode chip (70).

Fig. 2b shows an electrode (2) with which also EKG and EEG measurements can be carried out, among others. For discharging the action potentials, two electrode pins (76) (preferably coated with silver, gold or sintered material) are arranged in the electrode (2), said pins applying the action potentials to the input of a measuring amplifier (78) - see Fig. 7 for more details - by way of shielded cables (77). For establishing a good skin contact, the electrode pins are ideally fitted on the back side with mechanical springs (79). In order to avoid moisture bridges on the skin contact side, the electrode pins are framed by a special insulating coating (89). In addition, a great number of additional sensors such as temperature (80), skin moisture (81), motion (82) and oxygen saturation (83) sensors etc. are arranged in the electrode chip. The electrode chip (70) is realized in this connection by means of the two-layer technology, i.e., the elementary sensors (40a to 40i) are arranged on the side of the chip facing the skin, and, for example the sensor control unit (33), the transmitting/receiving (30, 31) and the frequency generation

(35) units etc. are arranged on the back side. The accumulator (38) for energy storage) is, in the present embodiment, arranged above the electrode chip (70).

Fig. 2c shows an electrode (2) having electrode pins (76) in the form of needles. Said electrode pins (76) penetrate the skin of the patient and lead to a reduction of the transition resistance, which permits more sensitive measurements. The antenna (36a) is integrated in the electrode chip (70) for reducing the size of the electrode (2) and for superior HF-transmission.

Various possibilities are available for the combination of sensors in one elcctrode; this is shown in Fig. 3 for various electrode arrangements.

The electrode(s) in the thoracic region (2a) comprise(s) EKG sensors with 2 to 4 tapping points for the action potentials (depending on the number of electrodes). The electrodes are shaped here, for example ovally or cloverleaf-like depending on the number of tapping points. One electrode is adequate for the monitoring of infants. Usefully, the electrode additionally comprises for control purposes an impedance sensor for measuring the transition resistance between the electrode and the skin. The transition resistance has an important bearing on the quality of the signals and should have values of lower than 5 to 10 kohm. In addition, the transition resistance between the

individual electrode pins of an electrode is tested in order to exclude any possible short circuit (e.g. due to excessive moisture of the skin, or common salt bridge — the resistance should not be significantly lower than about 500 ohm depending on the spacing of the electrode pins. Preferably, the evaluator station tests continuously whether said measured control values fall short of or exceed the preset upper and lower limits, especially for the purpose of avoiding false alarms. In addition, preferably an acceleration sensor is arranged in the electrode, which can measure also the cardiac activity, on the one hand, and serve as a reference measurement for the breathing, on the other hand. Further useful possibilities include the integration of a position sensor, a temperature sensor, as well as a reference sensor for the moisture measurement.

The electrode on the abdomen (2b) contains a sensor for monitoring the breathing (for example an acceleration sensor). By comparison with the data of the reference sensors (arranged, for example at 2a, 2e and/or 2f), it is possible to compensate or eliminate the influence of movements of the entire body, for example due to shocks in the carriage or during drives in the car.

The head electrode(s) (2c) contain(s) the EEG-sensors (shaped similar to the EKG - electrodes), which comprise 2 to 4 tapping points for the potential values as well. Due to the

lower EEG signals (lower than the EKG signals by about a factor 1000), the head electrodes, too, comprise for control purposes impedance sensors for measuring the transition resistance. In addition, it is possible also to arrange, for example a moisture sensor between the individual electrode pins of the EEG discharge line, in order to detect in this way a short circuit or a data falsification due to excessive moisture. This procedure, of course, is possible with the EKG discharge as well.

Another possibility for the breating control consists in the arrangement of an electrode in the facial region (2d), in particular between the mouth and the nose. With this electrode arrangement, the breathing can be measured by way of a temperature sensor. An alternative consists in monitoring the concentration of the exiting CO_2-content (basically also of the O_2-content) via a gas sensor. In addition, the respiratory activity can be monitored also by means of a moisture sensor by measuring the air humidity. With all three methods, a breathing activity is expressed by fluctuations in the ambient temperature, in the CO_2-content and the air humidity within the immediate proximity of the nose and mouth.

The electrode in the palm of the hand (2e), which basically can be attached also to the sole of the foot, contains a potential sensor (preferably a measuring amplifier), a capacity

sensor (capacity diode), or an electrocaloric sensor (the surface charge effects a change in temperature) for measuring the electrodermal activities or the SSR. It has been found recently that electric skin phenomena occur in infants in situations causing stress for the body, which phenomena can be detected in a simple way. Such phenomena are known from the lie detector technology. The measurement of said potentials opens new possibilities for a distinction of which events (for example breathing pauses, deceleration of the heart rate) are unimportant for the organism, and which one have to be viewed as threatening. It has been found that these signals are particularly pronounced on the palms of the hands and the soles of the feet, so that they can be registered best in said sites. Furthermore, the electrode contains a moisture sensor for measuring the moisture of the skin (perspiration) because it has been found that parallel with the SSR, stress situations cause secretion of sweat on the palms of the hands and soles of the feet. In addition, a reference sensor can be arranged in the electrodes for the breathing.

The electrode (2f) is preferably designed in the form of a finger clip (see Fig. 4). Basically, such a clip can be attached also to toes of the foot or to the bridge of the nose. It contains a sensor for measuring the oxygen saturation in the blood (pulsoximetry). The pulsoximetry takes place in this connection either by means of transmission measurement

or reflection measurement with optic wavelengths between 660 nm and 940 nm. The determination of the oxygen saturation in the blood is based on the spectral absorption of specific wavelengths on the red light and remore infrared range of hemoglobin and oxyhemoglobin when such radiation penetrates the skin, muscles and tissues. For these measurements, IR-light (88) or light is radiated by means of an emitting diode (e.g. Ga(Al,P)As and In(Ga)P-LED's), which penetrates the body parts with blood circulation, and which is then registered by a sensitive detector (e.g. GaAs-diode)(86). In connection with the more sensitive transmission measurements, the emitter and detector are arranged in separate units, which approximately oppose each other (as in the present exemplified embodiment). Pulsoximetry by means of reflection measurements can be carried out basically on all parts of the body (with suitable blood circulation), for example also in the thoracic region, whereby the emitter and the detector can be integrated in the same chip. Since pulsoximetric measurements react susceptibly to movements, an acceleration sensor (87) is preferably integrated in the fingerclip. With the measurement of the oxygen saturation it is possible also to monitor the pulse, among other things. This is shown on the curve (K) in the cutout of Fig. 4, which represents the absorption (A) versus time (T).

The electrode at (2g) is designed as an arm bracelet preferably made of elastic, flexible material. Especially for monitoring infants, this bracelet can be left permanently attached

because it causes no inconvenience. With this bracelet it is possible to tap the pulse, for example by way of pressure sensors, and thus to monitor the cardiac activity. A combination especially with temperature and moisture sensors, or ISFET's (perspiration), as well as with acceleration sensors is suitable.

The electrode (2h), which is shown in greater detail in Fig. 5, serves for monitoring the transcutaneous oxygen ($tcpO_2$) and carbon dioxide ($tcpCO_2$) contents in the blood. These measurements, which are useful especially on infants, offer continuous information about the ability of the body to supply the tissue with oxygen, and to discharge carbon dioxide via the cardiopulmonary system. The transcutaneous pO_2-value permits conclusions with respect to the arterial oxygen concentration and possible changes in the heart minute volume. $tcpO_2$- and $tcpCO_2$-measurements are based on the fact that an increase in the skin temperature (preferably temperatures between 38°C and 45°C) effects an increase in the blood circulation of the skin and of the oxygen and carbon dioxide partial pressure, and makes the skin permeable to the gas diffusion.

In the present exemplified embodiment, the individual sensors, transmitting and receiving units etc. of the electrode are not integrated in one chip. For warming up certain parts of the skin, a heating element (e.g. a heating resistor) or preferably

(for preventing burns in long-term applications) a heat radiator (90) (e.g. an IR-diode) is arranged on the side of the electrode facing the skin. A suitable temperature or radiation sensor (e.g. a pyroelectric sensor) (91) as well as a control unit (92) serve for the temperature control. An oxygen sensor (93) and a carbon dioxide sensor (94) then determine the gas concentrations (95) diffusing through the surface of the skin (96). The electrode (2h) is designed in such a way that the O_2-and CO_2-molecules flow directly past the gas sensors (93, 94). The electrode is preferably open at the top because the formation of moisture between the skin and the electrode can be more easily prevented in this way. For increasing the sensitivity and for protecting the sensors, the electrode can be closed at the top and/or at the bottom by a membrane (not shown here) that is permeable to gas. Alternatively to the electrodes (2) shown in the foregoing, the electrode has a transmitting diode (98) and a receiving diode (97) for the optical transmission of the data and commands from and to the evaluator station (1).

Another monitoring of the breathing is offered by the electrode (2i), which is arranged near the bronchial tube. In this connection, the noise of the respiratory flow is recorded by way of a miniaturized microphone and the flow of air is monitored in this way. The microphone can be realized in many different ways, preferably in the form of a capacitor

microphone or a piezoelectric microphone.

Said electrode (2i) is preferably combined with the electrode (2b) for monitoring the movement of the diaphragm. A distinction can be made in this way as to whether a central apnea (no movement of the diaphragm, no flow of air) - which apnea originates from the breathing center in the brain stem - is present, or an obstructive apnea (deglutition apnea; motion of the diaphragm, no flow of air).

For controlling and for avoiding false alarms, the individual electrodes may be quipped with additional control sensors, for example spacing sensors, which monitor the spacing between the electrode and the skin.

For infants, the fingerclip (2f) and the palm (2e) electrodes are ideally combined in one electrode. The measurement takes place in this connection preferably transversely across the palm of the hand, as shown in Fig. 6.

For measuring potential differences, it is basically possible to use one single operation amplifier. However, since the potentials to be measured have in the normal case a relatively high inner resistance, it is more useful to apply said potentials not directly to the input resistor of the subtracter. The use of impedance converters (potential sequencers) makes the operational mode of the subtracter independent of the inner

resistances of the measuring potentials. Fig. 7a shows such an exemplified embodiment for an operation amplifier circuit ((with a protective input circuit (99)) for difference formation, preamplification and filtering. Basically, it is possible also to arrange high-pass or bandpass filters upstream of the instrument or measuring amplifier (104) for suppressing the dc potential components.

The individual EEG or EKG signals of the electrode pins are, by way of the noninverting inputs of the operation amplifiers and impedance converters (100 and 101, respectively), supplied to the operation amplifier (102), and amplified. Higher inphase suppression is obtained through partial shifting of the potential amplification to the impedance converters. The advantage of this circuit is that the difference amplification can be adjusted by varying only one single resistor (103). With the electrometer amplifier (104), an operation amplification can be saved, if need be, if the symmetry of the circuit is dispensed with.

For dc potential separation and for the suppression of low-frequency noise (10 Hz, i.e., due to body movements), the amplified signals are then applied to the operation amplifier (105), which is wired as a high-pass filter of the first order with impedance conversion.

The component (106) represents an action low-pass filter with single positive feedback, by which the high-frequency redundant noise components of the measuring signal (e.g. caused by stray pick-up) are filtered out. The amplified and filtered potential finally can be tapped off between the potential points (120) and (121). The reference potential (121) is here applied to the battery/accumulator mass (characterized by the "-"-symbols), or the mass of the energy supply unit.

With electrode pins that are spaced far apart, or with galvanic connections between the electrodes, the highly resistive input leads (110, 111) are screened for preventing capacitive noise pick-up. The present exemplified embodiment contains for this purpose an operation amplifier (113) in an adding circuit (for forming the mean value of the tapped-off signals), to which the two outputs of the operation amplifiers (100 and 101) each are connected via a resistor. Since the formation of the sum on the operation amplifier (113) is inverting, an additional operation amplifier (114) is connected downstream, via which the averaged signals are supplied to the cable screening (112).

When using 3 or more electrode pins in one electrode, additional impedance converters, operation amplifiers and high- and low-pass filters are used. The connection (110), for example, can then be used as the reference point. An alternative is

that an analog multiplexer (arranged, for example, between the individual impedance converters (100, 101, ...) and the difference operation amplifier (102)) successively picks up the individual bio-potentials.

The module (104) shown can also be replaced by the circuit shown in Fig. 7b. As compared to the operation amplifiers/subtracters, said circuit offers the advantage that the amount of inphase suppression is here not dependent upon the pairing tolerance of the individual potential dividers. For this reason, it is possible to produce the circuit as a completely monolithically integrated circuit, whereas otherwise it is necessaryto realize the critical resistors separately, using the thin-layer technology. The symbols (+) and (-) represent in this connection supply voltage (125) for a constant current source.

Claims

1. Medical device for acquiring measured data, in particular for monitoring body functions, consisting of at least one electrode attached to a patient in connection with at least one evaluator station, whereby the electrode has a covering and at least one sensor for detecting an electric, physical, chemical or biological quantity and its conversion into an electric quantity, and privision is made within the covering for at least one converter converting the electric quantity generated by the sensor into a digital value, whereby the converter is actively connected to at least one transmitting unit, for which provision is made within the covering for the wireless digital data transmission, and the evaluator station has at least one receiving unit for receiving the data transmitted by the electrode, characterized in that the evaluator station (1) has at least one transmitting unit (6) for the wireless digital data transmission, and the electrode (2a, ..., 2f) within the covering (71) has at least one receiving unit (30) for receiving the data transmitted by the evaluator station (1), whereby the data transmitted by the evaluator station (1) control at least the data transmission of the electrode (2a, ..., 2f) and/or manipulate the data transmitted by the electrode.

2. Device according to claim 1, characterized in that the evaluator station (1) contains one or a plurality of decoding unit(s) (19) and that at least one electrode (2) is equipped with at least one encoding unit (45).

3. Device according to claim 1 or 2, characterized in that the evaluator station (1) contains one or a plurality of encoding unit(s) (22) and that at least one electrode (2) is equipped with at least one decoding unit (62).

4. Device according to one or several of claims 1 to 3, characterized in that the evaluator station (1) comprises at least one demultiplexer unit (20), and that at least one electrode (2) is equipped with at least one multiplexer unit (44).

5. Device according to one or several of claims 1 to 4, characterized in that the evaluator station (1) contains at least one multiplexer (21), and that at least one electrode (2) contains at least one demultiplexer (62).

6. Device according to one or several of claims 1 to 5, characterized in that the evaluator station (1) has at least one storage unit (8c) and/or at least one display unit (8a) and/or one or a plurality of alarm unit(s) (10).

Cl. 1

7. Device according to one or several of claims 1 to 6, characterized in that the evaluator station (1) and/or at least one electrode (2) has at least one electromagnetic detector (97) and/or emitter(98), the latter being designed as a semiconductor diode.

Cl. 1

8. Device according to one or several of claims 1 to 7, characterized in that the transmission control unit (7a) of the evaluator station (1) contains a cynchronization unit, and that the synchronization unit synchronizes the reference frequencies, oscillator frequencies, carrier frequencies, the cycle, the phase and/or the time frame of at least one electrode (2).

Cl. 1

9. Device according to one or several of claims 1 to 8, characterized in that the evaluator station (1) and/or at least one electrode (2) comprise(s) a transmission control unit (7a, 34).

Cl. 1

10. Device according to one or several of claims 1 to 9, characterized in that the evaluator station (1) contains a status unit (7c), the latter permitting the selection of the electrode (2) to be addressed and/or automatically recognizing which electrode(s) is/are connected and/or correctly connected to the body at the start of the diagnosis or monitoring.

11. Device according to one or several of claims 1 to 10, characterized in that the evaluator station (1) and/or at least one electrode (2) contain(s) an error diagnosis and/or correction unit (7d).

12. Device according to one or several of claims 1 to 11, characterized in that the evaluator station (1) contains a control unit (4b), the latter always adjusting the transmitting power of the signals of the electrode (2) and/or the evaluator station (1) to the minimum value required for still operating the circuit and/or transmitter (31) of the electrode (2); and that, if need be, if the transmitting power required by the electrode (2) and/or the evaluator station (1) is too high, the respective electrode no longer transmits signals to the evaluator station (1) and/or receives signals transmitted by the evaluator station (1).

13. Device according to one or several of claims 1 to 12, characterized in that the evaluator station (1) and/or at least one electrode (2) contain(s) a calibration unit (7c).

14. Device according to one or several of claims 1 to 13, characterized in that the evaluator station (1) has an interleaving unit (24) and/or a deleaving unit (18); and that at least one electrode (2) has a deleaving (61) and/or an interleaving unit (47).

15. Device according to one or several of claims 1 to 14, characterized in that at least one electrode (2) is attached to the skin surface (96).

16. Device according to one or several of claims 1 to 15, characterized in that at least one electrode (2) has at least one electrode pin (76) penetrating the body of the patient.

17. Device according to one or several of claims 1 to 16, characterized in that an evaluator unit (74) and/or a storage unit (33a) is/are arranged in at least one electrode (2).

18. Device according to one or several of claims 1 to 17, characterized in that a sensor control unit (33) is arranged in at least one electrode (2).

19. Device according to one or several of claims 1 to 18, characterized in that a training sequence unit (23, 46) for generating a test code is present in at least one electrode (2), and an equalizer (16, 59) is present in the evaluator station (1), or reversely.

20. Device according to one or several of claims 1 to 19, characterized in that the electrode (2) is at least partly supplied with energy by a high-frequency field emitted by the

evaluator station (1), and/or that at least one electrode (2) contains one or a plurality of accumulators (38) and/or at least one battery.

21. Device according to one or several of claims 1 to 20, characterized in that the electrode (2) has at least one antenna (36a), the latter being at least partly arranged in the electrode covering (71).

22. Device according to claim 21, characterized in that a reflector (36b) is arranged between the antenna (36a) and the side of the electrode covering (71) facing the skin.

23. Device according to one or several of claims 1 to 22, characterized in that at least one electrode (2) contains an identification unit (45a) for transmitting an identification code.

24. Device according to one or several of claims 1 to 23, characterized in that a reference element is arranged in the electrodes (2), said element serving for the determination of the own transmitting and/or high-frequency output(s).

25. Device according to one or several of claims 1 to 24, characterized in that the electrode (2) for error detection

contains one or a plurality of control sensor(s).

26. Device according to one or several of claims 1 to 25, characterized in that the individual electronic components of the electrode (2) are integrated in one single semiconductor chip (electrode chip)(76).

27. Device according to claim 26, characterized in that the transmitting and/or receiving antenna (36a) of the electrodes (2) is/are arranged in the electrode chip.

28. Device according to one or several of claims 1 to 27, characterized in that at least one sensor (40a, ..., 40i) of one electrode (2) is based on the field effect, bipolar transistor, diode, capacitor or AOW principle.

29. Device according to one or several of claims 1 to 28, characterized in that the electrodes (2) contain ion-sensitive, gas, acceleration, pressure, potential, impedance, current, magnetic field, temperature, position and/or radiation sensors (40a, ..., 40i).

30. Device according to one or several of claims 1 to 29, characterized in that two or a plurality of electrode pins (76) or tap-off points for measuring the bio-potentials (potentials, currents) are integrated in at least one electrode (2).

31. Device according to one or several of claims 1 to 30, for measuring the O_2-content and/or the CO_2-content in the blood, characterized in that the electrode (2) contains at least one light- or IR-light-emitting diode (85) radiating into tissue with blood circulation, as well as comprises one or a plurality of radiation-sensitive detector(s) (86) detecting the radiation transmitted and/or reflected by the blood.

32. Device according to one or several of claims 1 to 31, characterized in that the electrode (2) contains one or a plurality of impedance sensor(s) and/or at least one ISFET for measuring the moisture.

33. Device according to one or several of claims 1 to 32 for controlling the breathing, characterized in that at least two electrodes (2) are equipped with one or a plurality of acceleration sensor(s) and/or spacing sensors, whereby at least one electrode (2b) is arranged in the abdominal region and one or a plurality of electrode(s) (2a, 2c ... 2i) is/are arranged outside of the abdominal region, said electrode(s) serving as reference electrode(s).

34. Device according to one or several of claims 1 to 33 for controlling the breathing, characterized in that at least one electrode (2) contains one or a plurality of temperature

and/or gas and/or air humidity sensor(s), and that the electrode (2d) is attached near the nose and/or the mouth.

35. Device according to one or several of claims 1 to 34 for controlling the breathing, characterized in that at least one electrode (2d) contains one or a plurality of miniaturized microphone(s) , and that the electrode (2d) records the respiratory noise and is arranged near the larynx or the bronchial tube.

36. Device according to one or several of claims 1 to 35 for measuring the temperature, characterized in that the electrodes (2) contain thin-layer and/or thick-layer resistors and/or cold conductors and/or hot conductors and/or diodes and/or bipolar transistors and/or thermistors.

37. Device according to one or several of claims 1 to 36 for measuring the position, characterized in that at least one electrode (2) contains magnetic field sensors and/or inclination sensors and/or micromechanical sensors.

38. Method according to claim 37, characterized in that the data transfer between the evaluator station and the electrode(s) takes place in the simplex or half-doublex or full-doublex operation.

39. Method according to claim 37 or 38, characterized in that the data transfer takes place according to the ASK- and/or PSK- and/or FSK-method(s).

40. Method according to claim 37 or 38, characterized in that the data transfer takes place according to the PCM- and/or the DM-method(s).

41. Method according to one or several of claims 37 to 40, characterized in that the high-frequency transmission for the data transmission and/or the energy supply of the electrodes and/or the data transmission of the evaluator station take place on different frequencies.

42. Method according to one or several of claims 37 to 41, characterized in that the channel access takes place random-oriented, preferably according to the ALOHA- or CSMA- (carrier sense multiple access) or CSMA-CD- (CSMA with collision detection) method.

43. Method according to one or several of claims 37 to 42, characterized in that the channel access takes place according to a reservation method, preferably according to the TDMA- (time division multiple access) and/or FDMA- (frequency division MA) and/or CDMA- (code division MA) and/or space multiplex method and/or priority-oriented methods.

44. Method according to one or several of claims 37 to 43, characterized in that the HDLC-method is used for the data transmission.

45. Method according to one or several of claims 37 to 44, characterized in that the data transmission takes place by means of packets, whereby the packets contain start and stop bits and/or synchronization bits and/or useful information and/or a test code and/or sender address and/or receiver address.

ABSTRACT

A medical diagnosis and monitoring equipment has wireless electrodes, which are attached to the surface of the skin of the patient. The electrodes comprise a digital transmitting and receiving unit with antenna and microsensors. The electrodes can be used, among other things, for decting EEG- and EKG-signals, as well as for monitoring body/breathing movements, the temperature, perspiration, etc. A preferred exemplified embodiment comprises an electrode comprising all functions in a semiconductor chip which, as an integrated circuit, is equipped with the respective sensor, sensor control, frequency generation, transmitting and receiving units, as well as with a transmission control unit. The antenna is arranged in this connection in the flexible electrode covering or directly in the chip.

LIST OF REFERENCE SYMBOLS

1 Evaluator station
1a Removable module
2 Electrode
2a Chest electrode
2b Belly electrode
2c Head electrode
2d Face electrode
2e Hand palm electrode
2f Fingerclip electrode
2g Arm bracelet electrode
2h Electrode
2i Neck electrode
3 Patient
4 Receiving/transmitting separating filter
4a Receiving and transmitting antenna
4b Control/determination unit for transmitting output
5 Receiving unit
6 Transmitting unit
7 Evaluating unit
7a Transmission control unit
7b Sequence control unit
7c Status unit
7d Error diagnosis unit
7e Calibration unit
8a Display unit
8b Printer unit
8c Storage unit
9 Accumulator
10 Alarm unit
11 Frequency genration unit
12 High-frequency amplifier
13 Mixer
14 Low-frequency amplifier
15 Demodulator
16 Equalizer
17 Burst demultiplexer
18 Deleaving unit
19 Decoding unit
20 Demultiplexer
21 Digital multiplexer
22 Encoding unit
23 Training sequence unit
24 Interleaving unit
25 Burst multiplexer
26 Modulator
27 Low-frequency amplifier
28 Mixer
29 HF-transmission amplifier
30 Receiving unit
31 Transmitting unit
32 Sensor unit
33 Sensor control unit
33a Storage unit
33b Error diagnosis and correction unit
34 Transmission control unit
34a Sequence control unit

List of Reference Symbols (cont'd.)

35 Frequency generation unit
36 Antenna separating filter
36a Receiving and transmitting antenna
36b Reflector
37 Energy supply unit
38 Accumulator
40a-49i Elementary sensors
42 Analog multiplexer
43 Sensor-selective amplifier
44 Analog-to-digital converter
45 Enclding unit
45a Identification unit
46 Training sequence unit
47 Interleaving unit
48 Burst multiplexer
49 (PSK) modulator unit
50 Low-frequency amplifier
51 Mixer unit
52 High-frequency amplifier
55 High-frequency amplifier
56 Mixer
57 Low-frequency amplifier
58 Demodulator
59 Equalizer
60 Burst demultiplexer
61 Deleaving unit
62 Decoder
70 Electrode chip
71 Electrode covering
74 Evaluator unit
76 Electrode pin
77 Line
77a Lines, incl. chip (feed line)
78 Measuring amplifier
79 Spring
80 Temperature sensor
81 Skin moisture sensor
82 Movement sensor
83 Oxygen saturation sensor
85 LED
86 Light-sensitive detector
87 Acceleration sensor
88 Light or IR-light
89 Insulation layer
90 Heat radiator
91 Temperature or radiation sensor
92 Temperature control unit
93 Oxygen sensor
94 Carbon dioxide sensor
95 Blood gases
96 Skin surface
97 (LED/diode for receiving
98 (LED)/diode for transmitting (transmitting diode)
99 Input protection circuit
100-102 Operation amplifier
103 Resistor
104 Instrument or measuring amplifier

List of Reference Symbols (cont'd.)

105, 106	Operation amplifier
110, 111	High-resistive input
112	Screening
113, 114	Operation amplifier
120, 121	Potential point
121	Reference potential
125	Constant current source
(+), (-)	Supply voltages
A	Absorption
K	Curve
T	Time

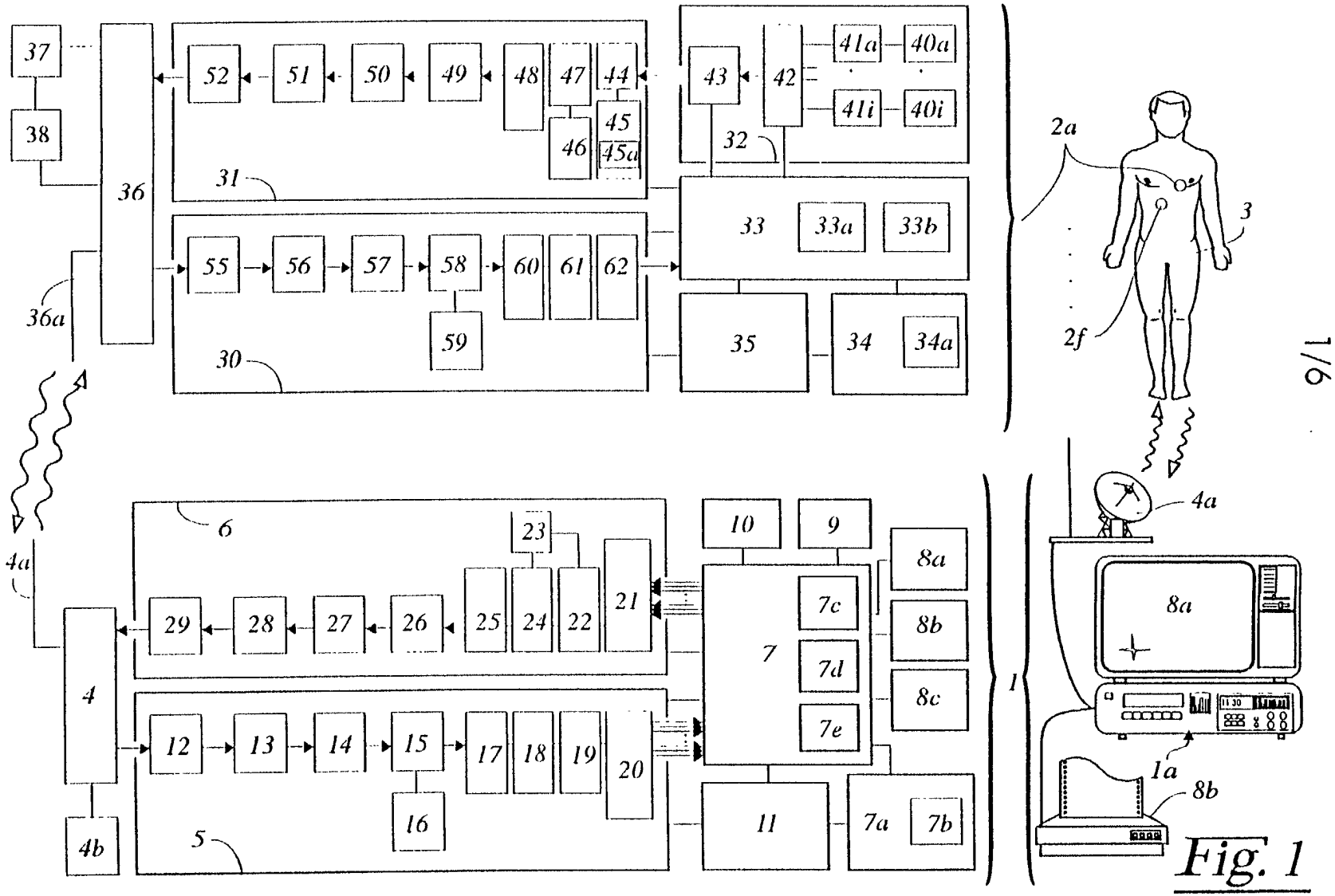


Fig. 1

1/6

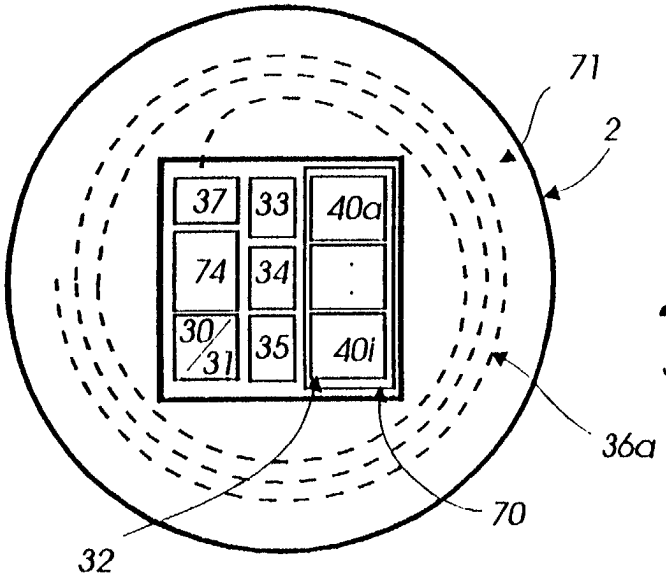


Fig. 2d

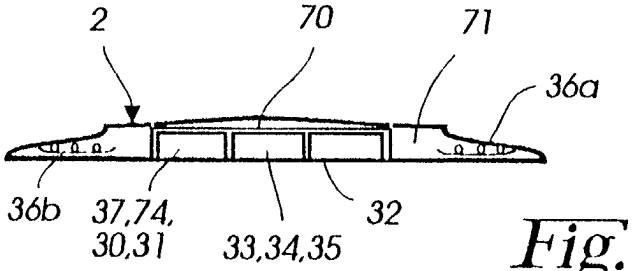


Fig. 2a

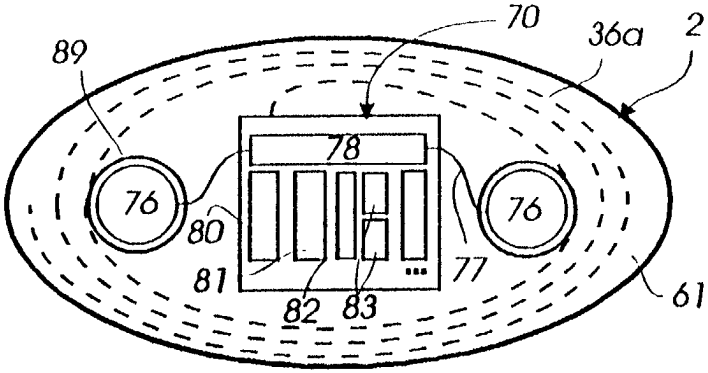


Fig. 2e

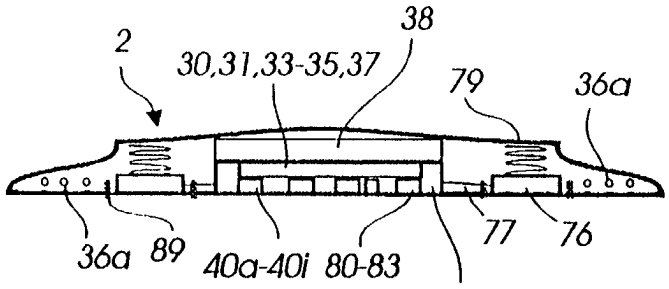
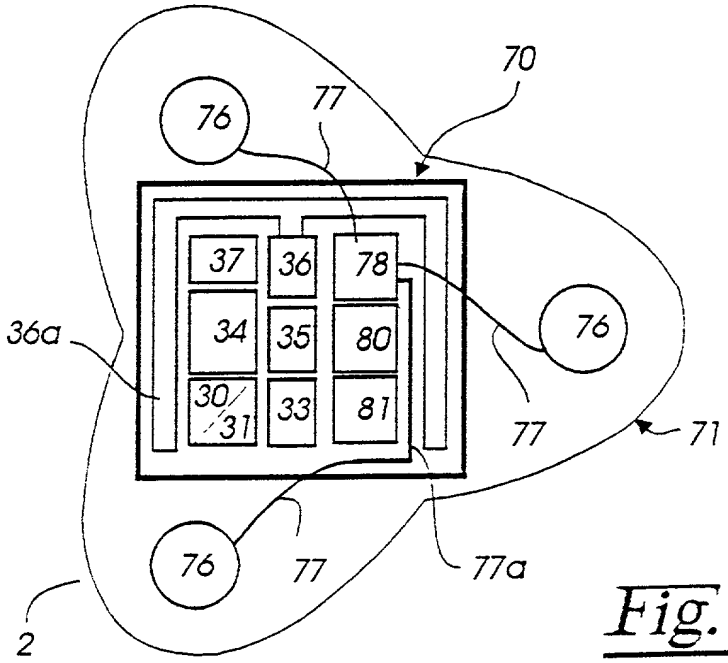


Fig. 2b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77a
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Fig. 2f

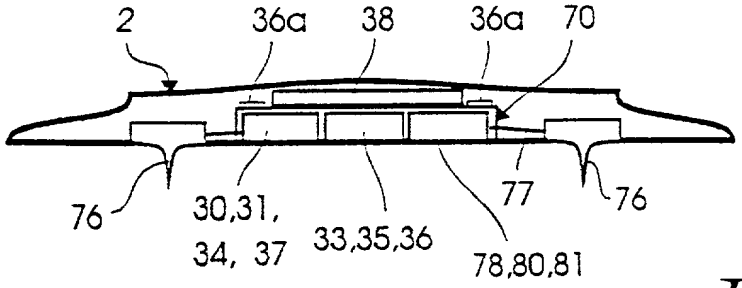
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Fig. 2c

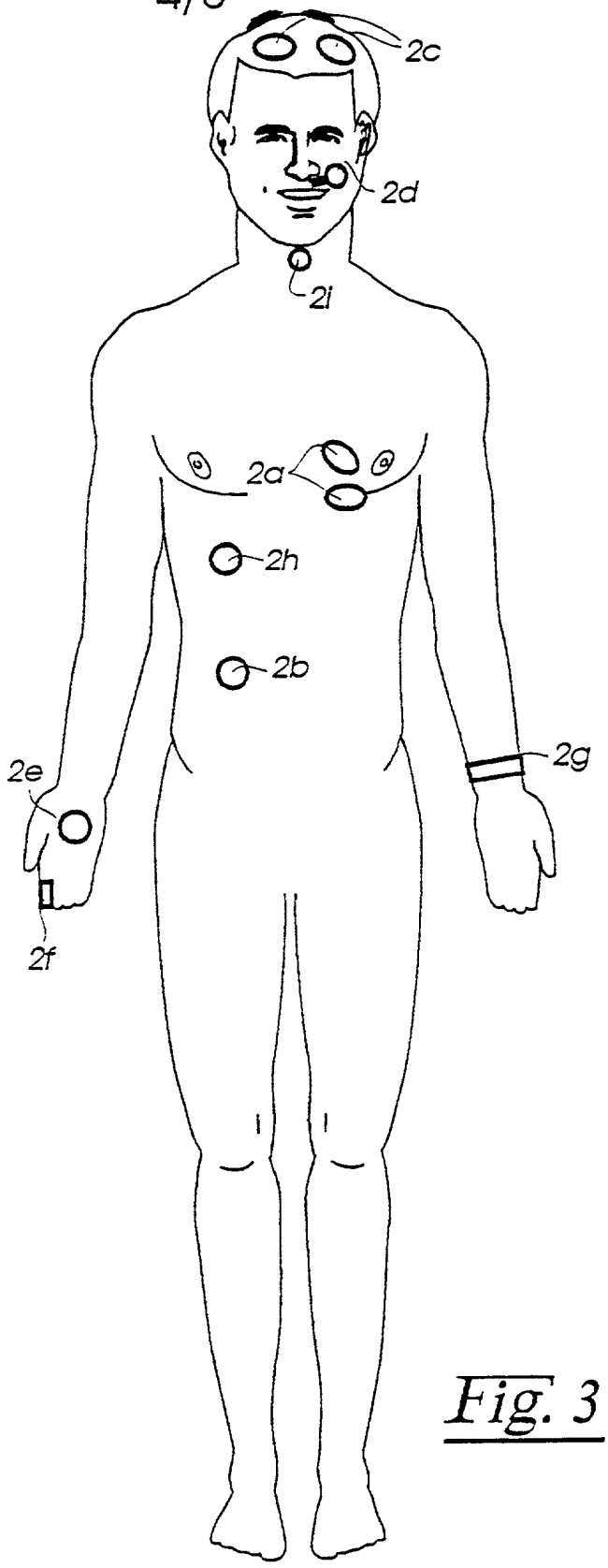

Fig. 3

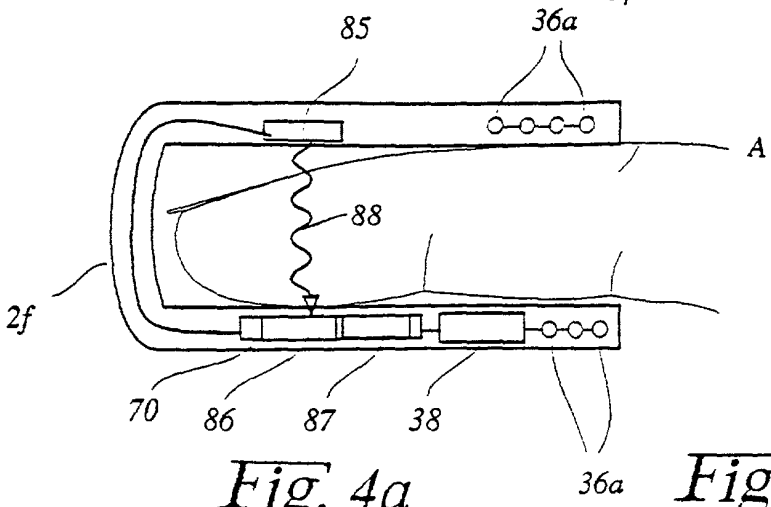

Fig. 4a

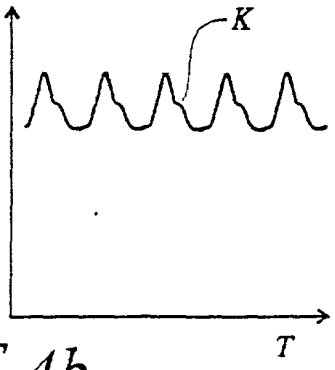

Fig. 4b

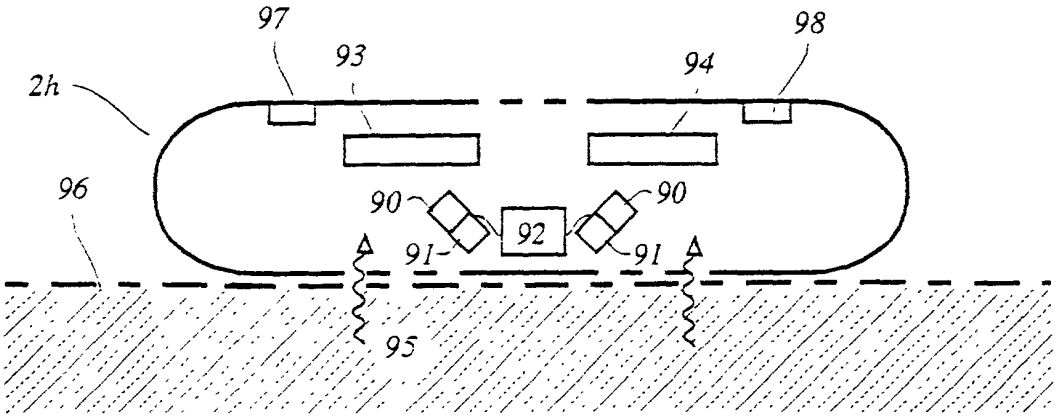

Fig. 5

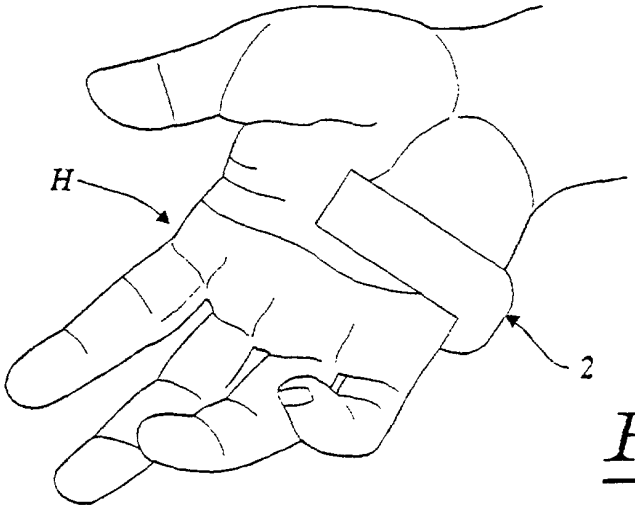

Fig. 6

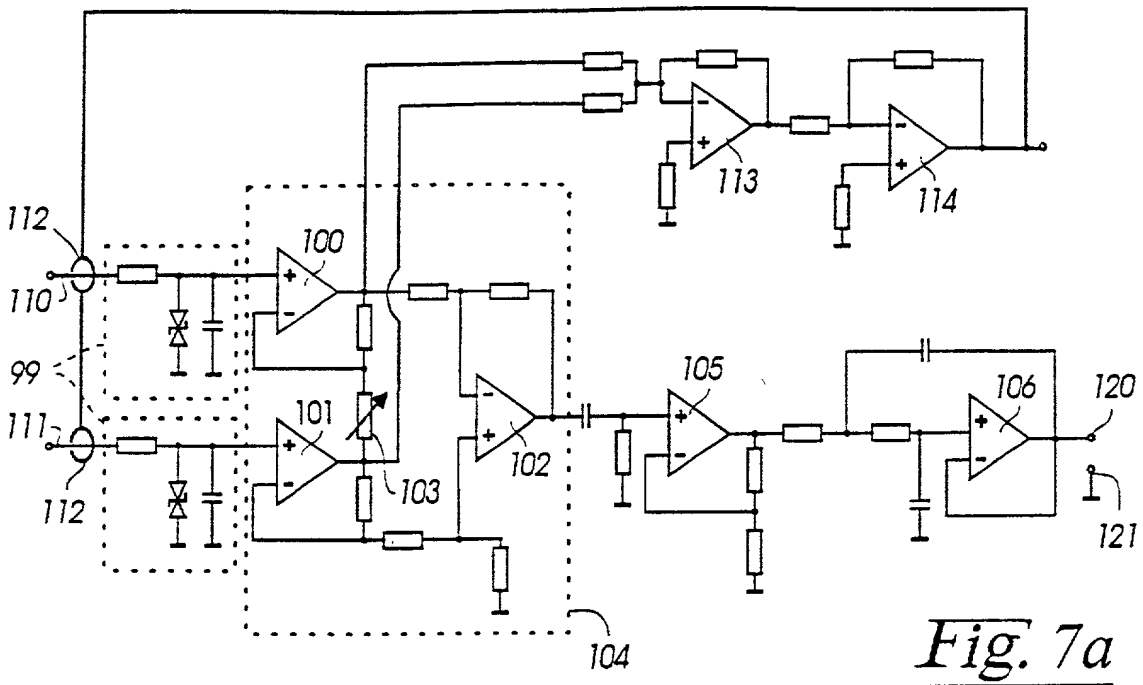
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Fig. 7a

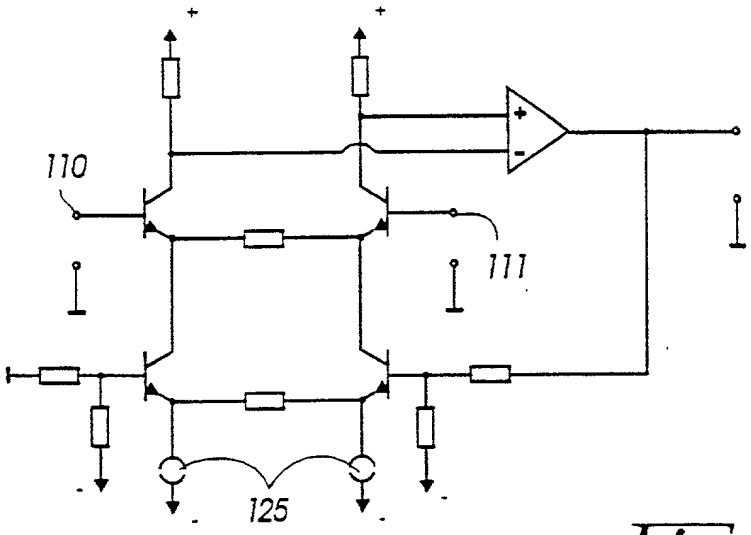
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Fig. 7b

COMBINED DECLARATION FOR PATENT APPLICATION AND POWER OF ATTORNEY
(Includes Reference to PCT International Applications)

ATTORNEY'S DOCKET NUMBER

As a below named inventor, I hereby declare that:

My residence, post office address and citizenship are as stated below next to my name,

I believe I am the original, first and sole inventor (if only one name is listed below) or an original, first and joint inventor (if plural names are listed below) of the subject matter which is claimed and for which a patent is sought on the invention entitled:

WIRELESS MEDICAL DIAGNOSIS AND MONITORING EQUIPMENT

the specification of which (check only one item below):

[ ] is attached hereto.

[ ] was filed as United States application

Serial No. _____

on _____,

and was amended

on _____ (if applicable).

[X] was filed as PCT international application

Number PCT/EP94/02926

on September 2, 1994,

and was amended under PCT Article 19

on _____ (if applicable).

I hereby state that I have reviewed and understand the contents of the above-identified specification, including the claims, as amended by any amendment referred to above.

I acknowledge the duty to disclose information which is material to the examination of this application in accordance with Title 37, Code of Federal Regulations, §1.56(a).

I hereby claim foreign priority benefits under Title 35, United States Code, §119 of any foreign application(s) for patent or inventor's certificate or of any PCT international application(s) designating at least one country other than the United States of America listed below and have also identified below any foreign application(s) for patent or inventor's certificate or any PCT international application(s) designating at least one country other than the United States of America filed by me on the same subject matter having a filing date before that of the application(s) of which priority is claimed:

PRIOR FOREIGN/PCT APPLICATION(S) AND ANY PRIORITY CLAIMS UNDER 35 U.S.C. 119:

COUNTRY (If PCT, indicate "PCT")	APPLICATION NUMBER	DATE OF FILING (day, month, year)	PRIORITY CLAIMED UNDER 35 USC 119
Germany	P 43 29 898.2	4 September 1993	[X] YES [ ] NO
			[ ] YES [ ] NO
			[ ] YES [ ] NO
			[ ] YES [ ] NO
			[ ] YES [ ] NO

I hereby claim the benefit under Title 35, United States Code, §120 of any United States application(s) or PCT international application(s) designating the United States of America that is/are listed below and, insofar as the subject matter of each of the claims of this application is not disclose in that/those prior application(s) in the manner provided by the first paragraph of Title 35, United States Code, §112, I acknowledge the duty to disclose material information as defined in Title 37, Code of Federal Regulations, §1.56(a) which occurred between the filing dates of the prior application(s) and the national or PCT international filing date of this application:

PRIOR U.S. APPLICATIONS OR PCT INTERNATIONAL APPLICATIONS DESIGNATING THE U.S. FOR BENEFIT UNDER 35 U.S.C. 120:

U.S. APPLICATIONS		STATUS (Check One)		
U.S. APPLICATION NUMBER	U.S. FILING DATE	PATENTED	PENDING	ABANDONED

PCT APPLICATIONS DESIGNATING THE U.S.					
PCT APPLICATION NO.	PCT FILING DATE	U.S. SERIAL NUMBERS ASSIGNED (if any)			

POWER OF ATTORNEY: As a named inventor, I hereby appoint the following attorney(s) and/or agent(s) to prosecute this application and transact all business in the Patent and Trademark Office connected therewith. *(List name and registration numbers):*

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I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

SIGNATURE OF INVENTOR 201	SIGNATURE OF INVENTOR 202	SIGNATURE OF INVENTOR 203
X Marcus Besson	X Gotthart v. Czettritz	X Ralph Bax
X DATE 29.02.96	DATE 28-2-96	DATE 25.02.96